

US3592232 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:22:05

All time stamps listed in this document are displayed in GMT

US3592232

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

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Participant ID

US3592232

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

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US3592232

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3592232

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Date of Birth (MMM yyyy)	(b) (6) 1941
Age	79
Age Units	YEARS
Age (Derived)	79
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3592232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	ASTIGMATISM BILATERAL
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	CATARACT RIGHT EYE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	FREQUENT URINARY TRACT INFECTIONS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Condition	PEDAL NEUROPATHY BILATERAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3592232

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:40
Height (xxx.x)	167.0 cm
Weight (xxx.x)	78.2 kg
BMI (xxx.x)	28.03973 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1985

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

VOLUNTEERS AT SCHOOLS

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:30:44

Generated On: 10 Jun 2021 08:22:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 186640

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☐   
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Height	ND - Not Done
Weight	ND - Not Done

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:40
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:53
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3592232

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:22 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	20 AUG 2020 11:40

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:22	20 AUG 2020 11:22
Nasopharyngeal Swab 2	No		



US3592232

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:59

PC Open Date & Time

20 AUG 2020 12:42

PC Close Date & Time

20 AUG 2020 15:12

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 16:09

PC Open Date & Time

20 AUG 2020 16:07

PC Close Date & Time

21 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

21 AUG 2020 16:42

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 14:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	26 AUG 2020 14:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:00

PC Open Date & Time

20 AUG 2020 12:42

PC Close Date & Time

20 AUG 2020 15:12

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 AUG 2020 16:07

PC Close Date & Time

21 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**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

21 AUG 2020 16:43

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**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

22 AUG 2020 19:03

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**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

23 AUG 2020 14:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**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

24 AUG 2020 13:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**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

25 AUG 2020 12:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**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

26 AUG 2020 14:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**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 ☐

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 13:01
PC Open Date & Time	20 AUG 2020 12:42
PC Close Date & Time	20 AUG 2020 15:12

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**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 ☐

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 16:07

PC Close Date & Time

21 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:44
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:03
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 14:34
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:15
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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 ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 14:37
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3592232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:30

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3592232

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:30

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

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)	21 SEP 2020
Time of assessment (00:00-23:59)	9:14 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 9:14
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3592232

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

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) 21 SEP 2020

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

Treatment Date and Time (derived) 21 SEP 2020 09:59

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



US3592232

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	9:30 (24 HR)
Collection date and time (derived)	21 SEP 2020 9:30

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:22	21 SEP 2020 9:22
Nasopharyngeal Swab 2	No		

US3592232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:28

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 SEP 2020 10:30

PC Open Date & Time

21 SEP 2020 10:19

PC Close Date & Time

21 SEP 2020 12:49

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	22 SEP 2020 11:39
PC Open Date & Time	21 SEP 2020 13:44
PC Close Date & Time	22 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

23 SEP 2020 11:42

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

24 SEP 2020 10:57

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 10:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**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

97.3 °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

26 SEP 2020 10:25

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 11:58

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 10:31

PC Open Date & Time

21 SEP 2020 10:19

PC Close Date & Time

21 SEP 2020 12:49

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**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

22 SEP 2020 11:40

PC Open Date & Time

21 SEP 2020 13:44

PC Close Date & Time

22 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**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

23 SEP 2020 11:43

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**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

24 SEP 2020 10:58

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**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

25 SEP 2020 10:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**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

26 SEP 2020 10:25

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**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

27 SEP 2020 11:58

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**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 ☐

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:31
PC Open Date & Time	21 SEP 2020 10:19
PC Close Date & Time	21 SEP 2020 12:49

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**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 ☐

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 11:41
PC Open Date & Time	21 SEP 2020 13:44
PC Close Date & Time	22 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 11:43
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2406

EAB) (1725)

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 10:58
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**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 ☒

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 10:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 10:26
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:43

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3592232

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:27

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	08:01 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:01
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

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.*

US3592232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	08:13 (24 HR)
Collection date and time (derived)	19 OCT 2020 08:13

US3592232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:29

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 10:31:58
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 07:53:14

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59



US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 13:40:58
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 15:48:55

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 09:03:15

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 08:59:58
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 17:05:46
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 10:40:08

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 08:28:28
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 JAN 2021 08:32:35
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 07:16:22

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 05:30:37
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 05:37:37

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 10:29:24

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59



US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 06:32:02
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 08:27:54

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 09:23:15

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 07:29:50
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 09:03:41
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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

20 MAR 2021 06:30:49

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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

27 MAR 2021 16:38:42

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 05:50:57

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59



US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 07:41:41
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 APR 2021 05:42:32
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

<b>TIMEPOINT</b>	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 <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	01 MAY 2021 06:26:05
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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 <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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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 <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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 NOV 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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11 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 DEC 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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25 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 DEC 2021 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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 <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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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 <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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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="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"/>



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**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 ☐

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3592232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

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"/>

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3592232

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:22:05

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		27 FEB 2021 09:23:27



US3592232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:58:47

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:58:47

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

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*

US3592232

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:39:50

Generated On: 10 Jun 2021 08:22:05

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

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 09:39:50

Generated On: 10 Jun 2021 08:22:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 08:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:39:50

Generated On: 10 Jun 2021 08:22:05

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.*

US3592232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:39:50

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	08:28 (24 HR)
Collection date and time (derived)	17 MAR 2021 08:28

US3592232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:39:49

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592232

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592232

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

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*



**US3592232**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592232

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:22:05

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3592232**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 08:22:05**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3592232

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

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

Visit date (dd MMM yyyy)	15 JAN 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
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US3592232

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Date of updated informed consent (dd MMM yyyy) 15 JAN 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) 15 JAN 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 \_\_\_\_\_

US3592232

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	15 JAN 2021 08:35

US3592232

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	08:32
Collection Date and Time (derived)	15 JAN 2021 08:32

US3592232

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID	USA-US103-2020-MRNA-1273-P30 1000001
Adverse event	RIGHT SUBCAPITAL FEMORAL NECK FRACTURE, DISPLACED GARDEN III
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 AUG 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 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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)	25 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	28 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

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

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

---

SUBJECT WAS CONTACTED ON  
27AUG2020 FOR SCHEDULED  
DAY 8 SAFETY PHONE CALL.

SHE REPORTED SHE  
SUSTAINED A FALL ON  
25AUG2020 WHICH RESULTED  
IN A RIGHT HIP FRACTURE. SHE  
HAD SURGERY ON 26AUG2020  
WHERE A PLATE AND  
PINS/SCREWS WERE TO REPAIR  
THE FRACTURE. AT THE TIME  
OF THE CALL SHE WAS STILL  
IN THE HOSPITAL.

RECORDS RECEIVED. X-RAY  
RIGHT HIP, RIGHT FEMUR  
25AUGUST2020 SHOWED  
SUBCAPITAL FRACTURE OF  
THE RIGHT PROXIMAL  
FEMUR/HIP. SUBJECT  
UNDERWENT ORIF OF THE  
RIGHT FEMORAL NECK WITH  
NO COMPLICATIONS. TO BE  
TOE TOUCH WEIGHTBEARING.  
SUBJECT CONFIRMS TRIPPED  
OVER A BABY GATE IN HER  
HOME. DISCHARGED HOME  
WITH FOUR WHEEL WALKER  
FOR MOBILIZATION.

---

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

---

US3592232

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID	
Adverse event	RIGHT HIP PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 AUG 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)	1 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID

Adverse event

CHEST WALL PAIN,  
MUSCULOSKELETAL,  
{SECONDARY TO FALL}

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID	
Adverse event	THYROID NODULE, RIGHT, BENIGN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID

Adverse event

AFEBRILE LEUKOCYTOSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID	
Adverse event	URINARY RETENTION
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)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 15:55:58

Generated On: 10 Jun 2021 08:22:05

AEID	
Adverse event	FALL
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 15:56:00

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

Yes ☒

No ☐

---

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

---



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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Name of Medication ALENDRONATE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPOROSIS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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Name of Medication AMLODIPINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 OCT 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 OCT 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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	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 APR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication VITAMIN D 3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:55:59

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP PAIN

Dose per administration 325

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

EVERY FOUR HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SUBCAPITAL FEMORAL  
NECK FRACTURE, DISPLACED  
GARDEN III

Dose per administration 100

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication MIRALAX

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SUBCAPITAL FEMORAL  
NECK FRACTURE, DISPLACED  
GARDEN III

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY RETENTION

Dose per administration .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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication APIXIBAN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)		1 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP PAIN, CHEST WALL PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 checked="" 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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication NITROFURANTOIN

Prophylaxis Yes ☐  
No ☒

Indication FREQUENT URINARY TRACT INFECTIONS

Dose per administration 100

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication ANCEF [CEFAZOLIN]

Prophylaxis Yes ☒  
No ☐

Indication PREOPERATIVE - HIP SURGERY

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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 checked="" 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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	26 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:55:59

Generated On: 10 Jun 2021 08:22:05

	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)		20 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 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"/>

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:56:00

Generated On: 10 Jun 2021 08:22:05

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 15:56:00

Generated On: 10 Jun 2021 08:22:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 AUG 2020	RIGHT FEMORAL NECK OPEN REDUCTION INTERNAL FIXATION	Adverse Event	
25 AUG 2020	MAGNETIC RESONANCE IMAGING	Adverse Event	
12 OCT 2020	THYROID SONOGRAM	Diagnostic	

US3592232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:22:05

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:22:05

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/AUG/2020 10:46
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



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/SEP/2020 21:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:58
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

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/OCT/2020 16:33
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

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 09:38:06

Generated On: 10 Jun 2021 08:22:05

SAEID	USA-US103-2020-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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:22
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.	True

Audit

US3592232 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

**US3592232**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:22:05**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Dec 2020 23:29:51
User entered 'US3592232'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:41:03

US3592232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:57:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 17:27:48

US3592232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:57:35
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:41:04



US3592232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[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 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:57:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 17:27:48

US3592232

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'SCRN'	System	20 Aug 2020 17:27:48

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered (b) (6) 1941'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:41:05

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '79'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'YEARS'	System	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '79'	System	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered 'Female (F)'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	20 Aug 2020 17:28:01



US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered 'l'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01



**US3592232**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:22:05**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:23
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 17:28:01

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Aug 2020'	System	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2020'	System	20 Aug 2020 17:28:11

**US3592232**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:22:05**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 17:28:11

**US3592232**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 17:28:11



US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 17:28:11

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:58:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:41:04

US3592232

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'l'	System	20 Aug 2020 17:28:17

US3592232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:59:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 17:28:17

US3592232

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:22:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:59:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:09:13

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:59:59
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:11:50
Data point term sent to Coder	System	21 Aug 2020 14:10:31
User entered 'astigmatism bilateral'	(b) (4), (b) (6)	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 09:44:30
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:44:24
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:00:01
User entered 'un UNK 1990'	(b) (4), (b) (6)	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:00:03
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:09:54



**US3592232**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:00:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:00:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:00:19
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 1990'	System	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '1990'	System	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:09:54

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:29
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:12:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:12:22
Data point term sent to Coder	System	21 Aug 2020 14:11:32
User entered 'cataract right eye'	(b) (4), (b) (6)	21 Aug 2020 14:10:38



**US3592232**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:30
User entered 'un UNK 2012'	(b) (4), (b) (6)	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:33
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:10:38

**US3592232**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:37
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:42
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2012'	System	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2012'	System	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:10:38



US3592232

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:10:38

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:02:54
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)	21 Aug 2020 14:12:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:12:20
Data point term sent to Coder	System	21 Aug 2020 14:11:35
User entered 'hypertension'	(b) (4), (b) (6)	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 15:21:46
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 15:21:46
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:02:56
User entered 'un UNK 2020'	(b) (4), (b) (6)	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:03:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:11:09

**US3592232**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:11:09

**US3592232**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:03:05
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:03:09
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2000'	System	07 Oct 2020 15:21:46
User entered 'Jan 2020'	System	21 Aug 2020 14:11:09



US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2000'	System	07 Oct 2020 15:21:46
User entered '2020'	System	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:11:09

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:07:38
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:13:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 14:13:24
Data point term sent to Coder	System	21 Aug 2020 14:12:40
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:07:41
User entered 'un UNK 2018'	(b) (4), (b) (6)	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:07:50
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:12:40

**US3592232**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:07:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:12:40

**US3592232**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:07:53
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:12:40



US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:09
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2018'	System	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2018'	System	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:12:40

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:16
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:14:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:14:22
Data point term sent to Coder	System	21 Aug 2020 14:13:42
User entered 'postmenopausal'	(b) (4), (b) (6)	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:19
User entered 'un UNK 1990'	(b) (4), (b) (6)	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:21
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:13:12



**US3592232**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:37
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:08:40
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 1990'	System	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '1990'	System	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:13:12

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:00
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Bladder disorders NEC, PT: Bladder prolapse, LLT: Bladder prolapse - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:15:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:15:13
Data point term sent to Coder	System	21 Aug 2020 14:14:44
User entered 'bladder prolapse'	(b) (4), (b) (6)	21 Aug 2020 14:13:54



US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:10
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:41
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:13:54

**US3592232**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:46
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:48
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2019'	System	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2019'	System	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:13:54



US3592232

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:13:54

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:16:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:16:22
Data point term sent to Coder	System	21 Aug 2020 14:15:46
User entered 'osteoporosis'	(b) (4), (b) (6)	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:11:00
User entered 'un UNK 2005'	(b) (4), (b) (6)	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:11:05
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:15:15

**US3592232**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:11:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:11:13
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:11:15
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2005'	System	21 Aug 2020 14:15:15



US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2005'	System	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:15:15

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:20
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:18:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:18:17
Data point term sent to Coder	System	21 Aug 2020 14:16:47
User entered 'anxiety'	(b) (4), (b) (6)	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:22
User entered 'un UNK 2018'	(b) (4), (b) (6)	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:25
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:15:57

**US3592232**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:31
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:57



US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:33
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2018'	System	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2018'	System	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:15:57

**US3592232**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:15:57

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:18:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:18:16
Data point term sent to Coder	System	21 Aug 2020 14:16:49
User entered 'hysterectomy'	(b) (4), (b) (6)	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:44
User entered 'un UNK 1998'	(b) (4), (b) (6)	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:46
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:16:36



US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:12:52
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 1998'	System	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '1998'	System	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	21 Aug 2020 14:16:36

US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:34:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:34:36
Data point term sent to Coder	System	29 Sep 2020 17:34:27
User entered 'frequent urinary tract infections'	(b) (4), (b) (6)	29 Sep 2020 17:33:51



**US3592232**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered 'un UNK 2013'	(b) (4), (b) (6)	29 Sep 2020 17:33:51

**US3592232**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:33:51

**US3592232**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:33:51

US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:33:51

**US3592232**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:33:51

US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2013'	System	29 Sep 2020 17:33:51

US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2013'	System	29 Sep 2020 17:33:51

US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	29 Sep 2020 17:33:51



US3592232

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	29 Sep 2020 17:33:51

US3592232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:22:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:31:04
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). 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)	28 Oct 2020 10:43:24
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:07:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:07:51
Data point term sent to Coder	System	29 Sep 2020 17:41:43
User entered 'PEDAL NEUROPATHY bilateral' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 17:41:33
User entered 'pedal neuropathy'	(b) (4), (b) (6)	29 Sep 2020 17:41:15

**US3592232**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered 'un UNK 2010'	(b) (4), (b) (6)	29 Sep 2020 17:41:15

**US3592232**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:41:15

**US3592232**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:41:15

**US3592232**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:41:15

**US3592232**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:30:07
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:41:15

US3592232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'Jan 2010'	System	29 Sep 2020 17:41:15



US3592232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:22:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '2010'	System	29 Sep 2020 17:41:15

US3592232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	29 Sep 2020 17:41:15

US3592232

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered empty.	System	29 Sep 2020 17:41:15

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:22
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:24
User entered '10:40'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered '20 Aug 2020 10:40'	System	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:26
User entered '167.0' cm	(b) (4), (b) (6)	21 Aug 2020 14:18:40
DataPoint set to visible.	System	20 Aug 2020 17:28:17



US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:28
User entered '78.2' kg	(b) (4), (b) (6)	21 Aug 2020 14:18:40
DataPoint set to visible.	System	20 Aug 2020 17:28:17

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
Amendment Manager: User entered '28.03973'	System	17 Sep 2020 00:16:05
User entered '28.0'	System	21 Aug 2020 14:18:40
DataPoint set to visible.	System	20 Aug 2020 17:28:17

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'kg/m2'	System	21 Aug 2020 14:18:40
DataPoint set to visible.	System	20 Aug 2020 17:28:17

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered '98.4' F	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:37
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered '71'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'bpm'	System	21 Aug 2020 14:18:40



US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'breaths/min'	System	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered '108'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'mmHg'	System	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:15:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:39
User entered '61'	(b) (4), (b) (6)	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User entered 'mmHg'	System	21 Aug 2020 14:18:40

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46

US3592232

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46



US3592232

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:04
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 19:59:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 19:59:22
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:16:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:18:57

US3592232

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:04
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 19:59:22
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 19:59:22
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:16:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:56:19
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:18:57

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:08
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:11
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:13
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:14
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:21
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:22
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:20:05



US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
User closed query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 05:56:46
Query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' answered with 'LMP and start date of post menopausal should not be the same.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:49:02
User opened query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:20:08
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:19:25
User entered 'un UNK 1985'	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:22:05

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:19:28
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:20:05

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:22:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:22:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:22:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:21:59
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:21:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'volunteers at schools'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:21:59



US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered 'l'	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:54
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:21:59

US3592232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:22:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:23:01



**US3592232**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:22:21
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:23:01

US3592232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[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 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:22:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 14:23:01

US3592232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'VISIT1'	System	21 Aug 2020 14:23:01

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:49:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:52:43
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:52:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:49:34
User entered '186640' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:49:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:49:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

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)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:23:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

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)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:23:34



US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:23:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:23:34

**US3592232**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:22:05**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:05
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:23:34

US3592232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:05

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:28:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:44:51

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '167.0' cm	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '78.2' kg	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '167.0' cm	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '78.2' kg	(b) (4), (b) (6)	21 Aug 2020 14:27:07



US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '10:40'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered '20 Aug 2020 10:40'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '98.4' F	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:27:07



US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '71'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'bpm'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'breaths/min'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '108'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'mmHg'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '61'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'mmHg'	System	21 Aug 2020 14:27:07



US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '167.0' cm	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:23:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:52:29
User entered '78.2' kg	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '12:53'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered '20 Aug 2020 12:53'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '97.7' F	(b) (4), (b) (6)	21 Aug 2020 14:27:07



US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '73'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'bpm'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'breaths/min'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '115'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'mmHg'	System	21 Aug 2020 14:27:07



US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:16
User entered '69'	(b) (4), (b) (6)	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'mmHg'	System	21 Aug 2020 14:27:07

US3592232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:17
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 19:59:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 19:59:36
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:27:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:27:27

US3592232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:17
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 19:59:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 19:59:36
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:27:56
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:27:27

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

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)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:29:10



US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered '12:22'	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
DataPoint Verified.		17 Sep 2020 15:32:47
User entered 'ONCE'	System	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:29:10

US3592232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:33:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:29:52

US3592232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:33:10
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:29:52



**US3592232**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:22:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:33:10
User entered '11:40'	(b) (4), (b) (6)	21 Aug 2020 14:29:52

US3592232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered '20 Aug 2020 11:40'	System	21 Aug 2020 14:29:52

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:34:48
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:34:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:30:20

**US3592232**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:34:53
User entered '11:22'	(b) (4), (b) (6)	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered '20 Aug 2020 11:22'	System	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		21 Aug 2020 14:30:20



US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:02
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:04
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered empty.	System	21 Aug 2020 14:30:20

US3592232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:30:47

US3592232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:36:50
User entered 'l'	System	21 Aug 2020 14:30:47

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T12:59:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e14d1e9f-893c-4fbf-b200-d936acc382e3'	System	20 Aug 2020 17:59:32
User entered 'Yes (Y)'	System	20 Aug 2020 17:59:32

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T12:59:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e14d1e9f-893c-4fbf-b200-d936acc382e3' User entered '97.7'	System	20 Aug 2020 17:59:32
	System	20 Aug 2020 17:59:32



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T12:59:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e14d1e9f-893c-4fbf-b200-d936acc382e3'	System	20 Aug 2020 17:59:32
User entered 'No (N)'	System	20 Aug 2020 17:59:32

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T12:59:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e14d1e9f-893c-4fbf-b200-d936acc382e3'	System	20 Aug 2020 17:59:32
User entered '20 Aug 2020 12:59'	System	20 Aug 2020 17:59:32

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 12:42'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 15:12'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T16:08:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '99fbdba2-ad94-4f3d-b863-9e218c333fa0'	System	20 Aug 2020 21:09:22
User entered 'Yes (Y)'	System	20 Aug 2020 21:09:22

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T16:09:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '99fbdba2-ad94-4f3d-b863-9e218c333fa0'	System	20 Aug 2020 21:09:22
User entered '97.7'	System	20 Aug 2020 21:09:22

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T16:09:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '99fbdba2-ad94-4f3d-b863-9e218c333fa0'	System	20 Aug 2020 21:09:22
User entered 'No (N)'	System	20 Aug 2020 21:09:22



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T16:09:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '99fbdba2-ad94-4f3d-b863-9e218c333fa0'	System	20 Aug 2020 21:09:22
User entered '20 Aug 2020 16:09'	System	20 Aug 2020 21:09:22

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 16:07'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 2'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9bd3159e-dffb-467c-b2b5-7725c8390b51'	System	21 Aug 2020 21:42:45
User entered 'Yes (Y)'	System	21 Aug 2020 21:42:45

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9bd3159e-dffb-467c-b2b5-7725c8390b51'	System	21 Aug 2020 21:42:45
User entered '96.6'	System	21 Aug 2020 21:42:45

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:32', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9bd3159e-dffb-467c-b2b5-7725c8390b51'	System	21 Aug 2020 21:42:45
User entered 'No (N)'	System	21 Aug 2020 21:42:45

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9bd3159e-dffb-467c-b2b5-7725c8390b51'	System	21 Aug 2020 21:42:45
User entered '21 Aug 2020 16:42'	System	21 Aug 2020 21:42:45



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 3'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:01:34', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15e548c8-33bc-4ece-bef8-2b002b67f550'	System	23 Aug 2020 00:02:12
User entered 'Yes (Y)'	System	23 Aug 2020 00:02:12

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:01:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15e548c8-33bc-4ece-bef8-2b002b67f550'	System	23 Aug 2020 00:02:12
User entered '96.7'	System	23 Aug 2020 00:02:12

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:01:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15e548c8-33bc-4ece-bef8-2b002b67f550'	System	23 Aug 2020 00:02:12
User entered 'No (N)'	System	23 Aug 2020 00:02:12

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:02:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15e548c8-33bc-4ece-bef8-2b002b67f550'	System	23 Aug 2020 00:02:12
User entered '22 Aug 2020 19:02'	System	23 Aug 2020 00:02:12

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 4'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:32:51', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd2e7254d-bcc6-4122-9e72-37aefa948aa8'	System	23 Aug 2020 19:33:16
User entered 'Yes (Y)'	System	23 Aug 2020 19:33:16

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:00', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd2e7254d-bcc6-4122-9e72-37aefa948aa8'	System	23 Aug 2020 19:33:16
User entered '98.0'	System	23 Aug 2020 19:33:16

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:05', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd2e7254d-bcc6-4122-9e72-37aefa948aa8'	System	23 Aug 2020 19:33:16
User entered 'No (N)'	System	23 Aug 2020 19:33:16

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd2e7254d-bcc6-4122-9e72-37aefa948aa8'	System	23 Aug 2020 19:33:16
User entered '23 Aug 2020 14:33'	System	23 Aug 2020 19:33:16

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 5'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:11', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '5bbd7411-cebc-40a2-8193-363089d1b902'	System	24 Aug 2020 18:14:36
User entered 'Yes (Y)'	System	24 Aug 2020 18:14:36

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '5bbd7411-cebc-40a2-8193-363089d1b902'	System	24 Aug 2020 18:14:36
User entered '97.2'	System	24 Aug 2020 18:14:36

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:23', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '5bbd7411-cebc-40a2-8193-363089d1b902'	System	24 Aug 2020 18:14:36
User entered 'No (N)'	System	24 Aug 2020 18:14:36

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '5bbd7411-cebc-40a2-8193-363089d1b902'	System	24 Aug 2020 18:14:36
User entered '24 Aug 2020 13:14'	System	24 Aug 2020 18:14:36

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 6'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:11:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f18631bf-c2d2-4dca-a0f5-8bfeb60e2497'	System	25 Aug 2020 17:12:20
User entered 'Yes (Y)'	System	25 Aug 2020 17:12:20

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f18631bf-c2d2-4dca-a0f5-8bfeb60e2497'	System	25 Aug 2020 17:12:20
User entered '96.7'	System	25 Aug 2020 17:12:20

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:04', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f18631bf-c2d2-4dca-a0f5-8bfeb60e2497'	System	25 Aug 2020 17:12:20
User entered 'No (N)'	System	25 Aug 2020 17:12:20

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f18631bf-c2d2-4dca-a0f5-8bfeb60e2497'	System	25 Aug 2020 17:12:20
User entered '25 Aug 2020 12:12'	System	25 Aug 2020 17:12:20

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 7'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:04', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	System	26 Aug 2020 19:35:52
User entered 'Yes (Y)'	System	26 Aug 2020 19:35:52



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	System	26 Aug 2020 19:35:52
User entered '98.0'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:25', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	System	26 Aug 2020 19:35:52
User entered 'Yes (Y)'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'the subject took Tylenol for hip pain' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 11:28:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	(b) (4), (b) (6)	02 Oct 2020 21:05:13
User entered '1'	System	26 Aug 2020 19:35:52
	System	26 Aug 2020 19:35:52
	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	System	26 Aug 2020 19:35:52
User entered '0'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:47', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'df4dfcc4-261f-4d84-8ae0-de9efa25a5c1'	System	26 Aug 2020 19:35:52
User entered '26 Aug 2020 14:35'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	26 Aug 2020 19:35:52
User entered 'Day 8'	System	26 Aug 2020 19:35:52



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:35:52



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	26 Aug 2020 19:35:52
User entered 'Day 9'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:35:52



US3592232

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T12:59:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7a5257-9688-44af-be9d-a0627ed40ef1'	System	20 Aug 2020 18:00:37
User entered 'None (1)'	System	20 Aug 2020 18:00:37

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7a5257-9688-44af-be9d-a0627ed40ef1'	System	20 Aug 2020 18:00:37
User entered 'No (N)'	System	20 Aug 2020 18:00:37

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7a5257-9688-44af-be9d-a0627ed40ef1'	System	20 Aug 2020 18:00:37
User entered 'No (N)'	System	20 Aug 2020 18:00:37

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7a5257-9688-44af-be9d-a0627ed40ef1'	System	20 Aug 2020 18:00:37
User entered 'None (1)'	System	20 Aug 2020 18:00:37

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7a5257-9688-44af-be9d-a0627ed40ef1'	System	20 Aug 2020 18:00:37
User entered '20 Aug 2020 13:00'	System	20 Aug 2020 18:00:37

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 12:42'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 15:12'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 16:07'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 2'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:54', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c4760534-9936-4949-ae7d-076bfbf809f6'	System	21 Aug 2020 21:43:31
User entered 'None (1)'	System	21 Aug 2020 21:43:31

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:42:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c4760534-9936-4949-ac7d-076bfbf809f6'	System	21 Aug 2020 21:43:31
User entered 'No (N)'	System	21 Aug 2020 21:43:31

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:05', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c4760534-9936-4949-ac7d-076bfbf809f6'	System	21 Aug 2020 21:43:31
User entered 'No (N)'	System	21 Aug 2020 21:43:31

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:11', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c4760534-9936-4949-ae7d-076bfbf809f6'	System	21 Aug 2020 21:43:31
User entered 'None (1)'	System	21 Aug 2020 21:43:31



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:25', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c4760534-9936-4949-ac7d-076bfbf809f6'	System	21 Aug 2020 21:43:31
User entered '21 Aug 2020 16:43'	System	21 Aug 2020 21:43:31

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 3'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:02:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'fe698bca-af9b-486a-9cea-7c6772b8a38e'	System	23 Aug 2020 00:03:05
User entered 'None (1)'	System	23 Aug 2020 00:03:05

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:02:34', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'fe698bca-af9b-486a-9cea-7c6772b8a38e'	System	23 Aug 2020 00:03:05
User entered 'No (N)'	System	23 Aug 2020 00:03:05

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:02:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'fe698bca-af9b-486a-9cea-7c6772b8a38e'	System	23 Aug 2020 00:03:05
User entered 'No (N)'	System	23 Aug 2020 00:03:05

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:02:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'fe698bca-af9b-486a-9cea-7c6772b8a38e'	System	23 Aug 2020 00:03:05
User entered 'None (1)'	System	23 Aug 2020 00:03:05



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'fe698bca-af9b-486a-9cea-7c6772b8a38e'	System	23 Aug 2020 00:03:05
User entered '22 Aug 2020 19:03'	System	23 Aug 2020 00:03:05

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 4'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:18', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'edb4cf97-afa2-430d-8dd7-b31990c7bc9f'	System	23 Aug 2020 19:33:45
User entered 'None (1)'	System	23 Aug 2020 19:33:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'edb4cf97-afa2-430d-8dd7-b31990c7bc9f'	System	23 Aug 2020 19:33:45
User entered 'No (N)'	System	23 Aug 2020 19:33:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:26', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'edb4cf97-afa2-430d-8dd7-b31990c7bc9f'	System	23 Aug 2020 19:33:45
User entered 'No (N)'	System	23 Aug 2020 19:33:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'edb4cf97-afa2-430d-8dd7-b31990c7bc9f'	System	23 Aug 2020 19:33:45
User entered 'None (1)'	System	23 Aug 2020 19:33:45



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'edb4cf97-afa2-430d-8dd7-b31990c7bc9f'	System	23 Aug 2020 19:33:45
User entered '23 Aug 2020 14:33'	System	23 Aug 2020 19:33:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 5'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '265588cd-5baf-4baa-95fe-5e7a28ad52c0'	System	24 Aug 2020 18:15:04
User entered 'None (1)'	System	24 Aug 2020 18:15:04

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:40', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '265588cd-5baf-4baa-95fe-5e7a28ad52c0'	System	24 Aug 2020 18:15:04
User entered 'No (N)'	System	24 Aug 2020 18:15:04

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:44', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '265588cd-5baf-4baa-95fe-5e7a28ad52c0'	System	24 Aug 2020 18:15:04
User entered 'No (N)'	System	24 Aug 2020 18:15:04

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:47', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '265588cd-5baf-4baa-95fe-5e7a28ad52c0'	System	24 Aug 2020 18:15:04
User entered 'None (1)'	System	24 Aug 2020 18:15:04



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:14:59', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '265588cd-5baf-4baa-95fe-5e7a28ad52c0'	System	24 Aug 2020 18:15:04
User entered '24 Aug 2020 13:14'	System	24 Aug 2020 18:15:04

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 6'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2f7c7c36-b320-40f8-94e8-f09f164fce16'	System	25 Aug 2020 17:12:45
User entered 'None (1)'	System	25 Aug 2020 17:12:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:25', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2f7c7c36-b320-40f8-94e8-f09f164fce16'	System	25 Aug 2020 17:12:45
User entered 'No (N)'	System	25 Aug 2020 17:12:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:28', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2f7c7c36-b320-40f8-94e8-f09f164fce16'	System	25 Aug 2020 17:12:45
User entered 'No (N)'	System	25 Aug 2020 17:12:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2f7c7c36-b320-40f8-94e8-f09f164fce16'	System	25 Aug 2020 17:12:45
User entered 'None (1)'	System	25 Aug 2020 17:12:45



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:40', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2f7c7c36-b320-40f8-94e8-f09f164fce16'	System	25 Aug 2020 17:12:45
User entered '25 Aug 2020 12:12'	System	25 Aug 2020 17:12:45

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 7'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:35:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '17f2a2a7-6665-47eb-baa8-67bd1ebe212c'	System	26 Aug 2020 19:36:17
User entered 'None (1)'	System	26 Aug 2020 19:36:17

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:00', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '17f2a2a7-6665-47eb-baa8-67bd1ebe212c'	System	26 Aug 2020 19:36:17
User entered 'No (N)'	System	26 Aug 2020 19:36:17

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '17f2a2a7-6665-47eb-baa8-67bd1ebe212c'	System	26 Aug 2020 19:36:17
User entered 'No (N)'	System	26 Aug 2020 19:36:17

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:06', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '17f2a2a7-6665-47eb-baa8-67bd1ebe212c'	System	26 Aug 2020 19:36:17
User entered 'None (1)'	System	26 Aug 2020 19:36:17



US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '17f2a2a7-6665-47eb-baa8-67bd1ebe212c'	System	26 Aug 2020 19:36:17
User entered '26 Aug 2020 14:36'	System	26 Aug 2020 19:36:17

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:43', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:47', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:00:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:01:00', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:01:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'None (0)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:01:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered 'No (N)'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-20T13:01:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ecaedbab-5c31-4f6d-bff7-aaa0168cf391'	System	20 Aug 2020 18:01:32
User entered '20 Aug 2020 13:01'	System	20 Aug 2020 18:01:32

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 12:42'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 15:12'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '20 Aug 2020 16:07'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 2'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:42', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:43:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:44:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'None (0)'	System	21 Aug 2020 21:44:39



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:44:16', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered 'No (N)'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-21T16:44:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '6292bbf3-efde-4c52-9ca6-c57b7ac409e7'	System	21 Aug 2020 21:44:39
User entered '21 Aug 2020 16:44'	System	21 Aug 2020 21:44:39

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 3'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:11', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:16', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:24', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ea84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'None (0)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:38', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ea84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered 'No (N)'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-22T19:03:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ff2a17da-ca84-40a1-8e54-f2a6c8586345'	System	23 Aug 2020 00:03:50
User entered '22 Aug 2020 19:03'	System	23 Aug 2020 00:03:50

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 4'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:51', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:33:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:04', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:08', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'None (0)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered 'No (N)'	System	23 Aug 2020 19:34:37

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-23T14:34:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f0e0f61e-65fe-4f5c-bc1b-9440a21b5d82'	System	23 Aug 2020 19:34:37
User entered '23 Aug 2020 14:34'	System	23 Aug 2020 19:34:37



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 5'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:06', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:13', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:16', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'None (0)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered 'No (N)'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-24T13:15:36', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2439a827-5a7e-45b3-8247-fe54222137a6'	System	24 Aug 2020 18:15:42
User entered '24 Aug 2020 13:15'	System	24 Aug 2020 18:15:42

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 6'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:47', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:56', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:12:59', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:13:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered 'None (0)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:13:09', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afac'	System	25 Aug 2020 17:13:21
User entered 'No (N)'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-25T12:13:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b9dee36b-7a42-4511-b8bb-1ceb6590afae'	System	25 Aug 2020 17:13:21
User entered '25 Aug 2020 12:13'	System	25 Aug 2020 17:13:21

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:29:10



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 7'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:38', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'None (0)'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:36:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered 'Yes (Y)'	System	26 Aug 2020 19:37:10



US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-08-26T14:37:05', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '71f143c9-90f6-4db0-ab09-61c8905ea0ae'	System	26 Aug 2020 19:37:10
User entered '26 Aug 2020 14:37'	System	26 Aug 2020 19:37:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	26 Aug 2020 19:35:52
User entered 'Day 8'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:35:52



US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	26 Aug 2020 19:35:52
User entered 'Day 9'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:35:52

US3592232

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:35:52

**US3592232**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:13:47

US3592232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:17
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:13:47

US3592232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 14:13:47



US3592232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:17
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:13:47

US3592232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:56:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:13:56

US3592232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:36
User entered 'l'	System	28 Aug 2020 14:13:56

US3592232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:58:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 14:50:13

US3592232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:58:10
User entered '3 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 14:50:13

US3592232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:58:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 14:50:13

US3592232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:58:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:50:13

US3592232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:00:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 14:50:37



**US3592232**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User entered 'l'	System	04 Sep 2020 14:50:37

**US3592232**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:41:22
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	15 Jan 2021 15:17:43

**US3592232**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:41:22
User entered '10 Sep 2020'	Diandra Henriques (b) (4) (b) (4)	15 Jan 2021 15:17:43

**US3592232**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:41:22
User entered 'Contact Made (CONTACT MADE)'	Diandra Henriques (b) (4) (b) (4)	15 Jan 2021 15:17:43

US3592232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:41:22
User entered empty.	Diandra Henriques (b) (4) (b) (4)	15 Jan 2021 15:17:43

US3592232

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
User closed query 'Please enter Safety Call Day 22 as it was done on 10 Sep 2020. Confirm with source on file.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:41:16
Query 'Please enter Safety Call Day 22 as it was done on 10 Sep 2020. Confirm with source on file.' answered with 'entered' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	15 Jan 2021 15:17:56
User opened query 'Please enter Safety Call Day 22 as it was done on 10 Sep 2020. Confirm with source on file.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 19:47:53
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:45:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:02:45

**US3592232**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User entered 'l'	System	21 Sep 2020 15:02:45

US3592232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:29:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:08:58



**US3592232**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:29:13
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:08:58

US3592232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:29:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 16:08:58

US3592232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'VISIT2'	System	22 Sep 2020 16:08:58

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '9:14'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '21 Sep 2020 9:14'	System	22 Sep 2020 16:11:20



US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '98.4' F	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '82'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'bpm'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'breaths/min'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '116'	(b) (4), (b) (6)	22 Sep 2020 16:11:20



US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '78'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '10:32'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '21 Sep 2020 10:32'	System	22 Sep 2020 16:11:20



US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '98.1' F	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '74'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'bpm'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'breaths/min'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '118'	(b) (4), (b) (6)	22 Sep 2020 16:11:20



US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:31
User entered '70'	(b) (4), (b) (6)	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	22 Sep 2020 16:11:20

US3592232

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:11:36

US3592232

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:41
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:11:36

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

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)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:03:05



US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered '09:59'	(b) (4), (b) (6)	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '21 Sep 2020 09:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:31:58
User entered 'ONCE'	System	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:03:05

US3592232

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:12:24



US3592232

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:59
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:12:24

**US3592232**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:22:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:28:59
User entered '9:30'	(b) (4), (b) (6)	22 Sep 2020 16:12:24

US3592232

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '21 Sep 2020 9:30'	System	22 Sep 2020 16:12:24

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:07
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

**US3592232**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

**US3592232**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:22:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:07
User entered '9:22'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '21 Sep 2020 9:22'	System	22 Sep 2020 16:12:53



US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:07
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered empty.	System	22 Sep 2020 16:12:53

US3592232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:13:09

US3592232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'I'	System	22 Sep 2020 16:13:09

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4edbf18-d5b2-48da-b547-7b7f5c302e74'	System	21 Sep 2020 15:30:33
User entered 'Yes (Y)'	System	21 Sep 2020 15:30:33



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4edbf18-d5b2-48da-b547-7b7f5c302e74'	System	21 Sep 2020 15:30:33
User entered '98.1'	System	21 Sep 2020 15:30:33

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4edbf18-d5b2-48da-b547-7b7f5c302e74'	System	21 Sep 2020 15:30:33
User entered 'No (N)'	System	21 Sep 2020 15:30:33

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:26', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4edbf18-d5b2-48da-b547-7b7f5c302e74'	System	21 Sep 2020 15:30:33
User entered '21 Sep 2020 10:30'	System	21 Sep 2020 15:30:33

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 10:19'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 12:49'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:39:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '7179d4e6-0517-44b4-93c5-f522a9458dd7'	System	22 Sep 2020 16:40:03
User entered 'Yes (Y)'	System	22 Sep 2020 16:40:03

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:39:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '7179d4e6-0517-44b4-93c5-f522a9458dd7'	System	22 Sep 2020 16:40:03
User entered '98.0'	System	22 Sep 2020 16:40:03



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:39:46', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '7179d4e6-0517-44b4-93c5-f522a9458dd7'	System	22 Sep 2020 16:40:03
User entered 'No (N)'	System	22 Sep 2020 16:40:03

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:39:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '7179d4e6-0517-44b4-93c5-f522a9458dd7'	System	22 Sep 2020 16:40:03
User entered '22 Sep 2020 11:39'	System	22 Sep 2020 16:40:03

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 13:44'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 2'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2a3eecd-fa3f-46c0-91c9-886c9329b650'	System	23 Sep 2020 16:42:56
User entered 'Yes (Y)'	System	23 Sep 2020 16:42:56

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2a3eecd-fa3f-46c0-91c9-886c9329b650'	System	23 Sep 2020 16:42:56
User entered '97.3'	System	23 Sep 2020 16:42:56

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2a3eecd-fa3f-46c0-91c9-886c9329b650'	System	23 Sep 2020 16:42:56
User entered 'No (N)'	System	23 Sep 2020 16:42:56



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2a3eecd-fa3f-46c0-91c9-886c9329b650'	System	23 Sep 2020 16:42:56
User entered '23 Sep 2020 11:42'	System	23 Sep 2020 16:42:56

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 3'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '140eb6d6-3dc4-4d7b-a571-d91039803157'	System	24 Sep 2020 15:57:46
User entered 'Yes (Y)'	System	24 Sep 2020 15:57:46

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '140eb6d6-3dc4-4d7b-a571-d91039803157'	System	24 Sep 2020 15:57:46
User entered '97.3'	System	24 Sep 2020 15:57:46

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '140eb6d6-3dc4-4d7b-a571-d91039803157'	System	24 Sep 2020 15:57:46
User entered 'No (N)'	System	24 Sep 2020 15:57:46

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:38', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '140eb6d6-3dc4-4d7b-a571-d91039803157'	System	24 Sep 2020 15:57:46
User entered '24 Sep 2020 10:57'	System	24 Sep 2020 15:57:46



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 4'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:43:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e9b06635-026e-4ffe-a78b-d9834d1e087a'	System	25 Sep 2020 15:44:04
User entered 'Yes (Y)'	System	25 Sep 2020 15:44:04

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:43:47', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e9b06635-026e-4ffe-a78b-d9834d1e087a' User entered '97.2'	System	25 Sep 2020 15:44:04
	System	25 Sep 2020 15:44:04

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:43:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e9b06635-026e-4ffe-a78b-d9834d1e087a'	System	25 Sep 2020 15:44:04
User entered 'No (N)'	System	25 Sep 2020 15:44:04

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:43:56', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e9b06635-026e-4ffe-a78b-d9834d1e087a'	System	25 Sep 2020 15:44:04
User entered '25 Sep 2020 10:43'	System	25 Sep 2020 15:44:04

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 5'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b690fc3c-7139-4e15-b3bd-6d9e64b400ff'	System	26 Sep 2020 15:25:29
User entered 'Yes (Y)'	System	26 Sep 2020 15:25:29

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b690fc3c-7139-4e15-b3bd-6d9e64b400ff' User entered '97.3'	System	26 Sep 2020 15:25:29
	System	26 Sep 2020 15:25:29

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b690fc3c-7139-4e15-b3bd-6d9e64b400ff'	System	26 Sep 2020 15:25:29
User entered 'No (N)'	System	26 Sep 2020 15:25:29

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b690fc3c-7139-4e15-b3bd-6d9e64b400ff'	System	26 Sep 2020 15:25:29
User entered '26 Sep 2020 10:25'	System	26 Sep 2020 15:25:29

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 6'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:57:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '480bee63-7a32-49f5-9e1e-b8dd6b9086c8'	System	27 Sep 2020 16:58:19
User entered 'Yes (Y)'	System	27 Sep 2020 16:58:19

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:57:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '480bee63-7a32-49f5-9e1e-b8dd6b9086c8' User entered '97.8'	System	27 Sep 2020 16:58:19
	System	27 Sep 2020 16:58:19

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '480bee63-7a32-49f5-9e1e-b8dd6b9086c8'	System	27 Sep 2020 16:58:19
User entered 'No (N)'	System	27 Sep 2020 16:58:19

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '480bee63-7a32-49f5-9e1e-b8dd6b9086c8'	System	27 Sep 2020 16:58:19
User entered '27 Sep 2020 11:58'	System	27 Sep 2020 16:58:19

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 7'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:43', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'a6ec7995-ec87-40cb-8a8c-cdd8ff3ba98c'	System	21 Sep 2020 15:31:19
User entered 'None (1)'	System	21 Sep 2020 15:31:19

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'a6ec7995-ec87-40cb-8a8c-cdd8ff3ba98c'	System	21 Sep 2020 15:31:19
User entered 'No (N)'	System	21 Sep 2020 15:31:19

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:30:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'a6ec7995-ec87-40cb-8a8c-cdd8ff3ba98c'	System	21 Sep 2020 15:31:19
User entered 'No (N)'	System	21 Sep 2020 15:31:19

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'a6ec7995-ec87-40cb-8a8c-cdd8ff3ba98c'	System	21 Sep 2020 15:31:19
User entered 'None (1)'	System	21 Sep 2020 15:31:19

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'a6ec7995-ec87-40cb-8a8c-cdd8ff3ba98c'	System	21 Sep 2020 15:31:19
User entered '21 Sep 2020 10:31'	System	21 Sep 2020 15:31:19

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 10:19'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 12:49'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:40:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dc3043fe-ad1f-49ee-b85a-b831a72945c1'	System	22 Sep 2020 16:40:58
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 16:40:58

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:40:21', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dc3043fe-ad1f-49ee-b85a-b831a72945c1'	System	22 Sep 2020 16:40:58
User entered 'No (N)'	System	22 Sep 2020 16:40:58

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:40:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dc3043fe-ad1f-49ee-b85a-b831a72945c1'	System	22 Sep 2020 16:40:58
User entered 'No (N)'	System	22 Sep 2020 16:40:58

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:40:39', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dc3043fe-ad1f-49ee-b85a-b831a72945c1'	System	22 Sep 2020 16:40:58
User entered 'None (1)'	System	22 Sep 2020 16:40:58

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:40:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dc3043fe-ad1f-49ee-b85a-b831a72945c1'	System	22 Sep 2020 16:40:58
User entered '22 Sep 2020 11:40'	System	22 Sep 2020 16:40:58

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 13:44'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 2'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:56', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '3bc4e9be-7526-4bac-b46e-630d51c2c4b3'	System	23 Sep 2020 16:43:21
User entered 'None (1)'	System	23 Sep 2020 16:43:21

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:42:59', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '3bc4e9be-7526-4bac-b46e-630d51c2c4b3'	System	23 Sep 2020 16:43:21
User entered 'No (N)'	System	23 Sep 2020 16:43:21

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '3bc4e9be-7526-4bac-b46e-630d51c2c4b3'	System	23 Sep 2020 16:43:21
User entered 'No (N)'	System	23 Sep 2020 16:43:21

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:06', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '3bc4e9be-7526-4bac-b46e-630d51c2c4b3'	System	23 Sep 2020 16:43:21
User entered 'None (1)'	System	23 Sep 2020 16:43:21

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:14', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '3bc4e9be-7526-4bac-b46e-630d51c2c4b3'	System	23 Sep 2020 16:43:21
User entered '23 Sep 2020 11:43'	System	23 Sep 2020 16:43:21

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 3'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0761062c-52ff-42b3-b652-ed6b383bc687'	System	24 Sep 2020 15:58:08
User entered 'None (1)'	System	24 Sep 2020 15:58:08

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0761062c-52ff-42b3-b652-ed6b383bc687'	System	24 Sep 2020 15:58:08
User entered 'No (N)'	System	24 Sep 2020 15:58:08

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:51', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0761062c-52ff-42b3-b652-ed6b383bc687'	System	24 Sep 2020 15:58:08
User entered 'No (N)'	System	24 Sep 2020 15:58:08

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:57:55', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0761062c-52ff-42b3-b652-ed6b383bc687'	System	24 Sep 2020 15:58:08
User entered 'None (1)'	System	24 Sep 2020 15:58:08

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0761062c-52ff-42b3-b652-ed6b383bc687'	System	24 Sep 2020 15:58:08
User entered '24 Sep 2020 10:58'	System	24 Sep 2020 15:58:08

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 4'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '718ccfb1-d2a1-461a-9ba3-bab8498b064f'	System	25 Sep 2020 15:44:54
User entered 'None (1)'	System	25 Sep 2020 15:44:54

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '718ccfb1-d2a1-461a-9ba3-bab8498b064f'	System	25 Sep 2020 15:44:54
User entered 'No (N)'	System	25 Sep 2020 15:44:54

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '718ccfb1-d2a1-461a-9ba3-bab8498b064f'	System	25 Sep 2020 15:44:54
User entered 'No (N)'	System	25 Sep 2020 15:44:54

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '718ccfb1-d2a1-461a-9ba3-bab8498b064f'	System	25 Sep 2020 15:44:54
User entered 'None (1)'	System	25 Sep 2020 15:44:54

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '718ccfb1-d2a1-461a-9ba3-bab8498b064f' User entered '25 Sep 2020 10:44'	System	25 Sep 2020 15:44:54
	System	25 Sep 2020 15:44:54

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 5'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:28', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96444533-6003-4ab8-b3bf-2885147f0052'	System	26 Sep 2020 15:25:56
User entered 'None (1)'	System	26 Sep 2020 15:25:56

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:32', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96444533-6003-4ab8-b3bf-2885147f0052'	System	26 Sep 2020 15:25:56
User entered 'No (N)'	System	26 Sep 2020 15:25:56

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96444533-6003-4ab8-b3bf-2885147f0052'	System	26 Sep 2020 15:25:56
User entered 'No (N)'	System	26 Sep 2020 15:25:56

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:42', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96444533-6003-4ab8-b3bf-2885147f0052'	System	26 Sep 2020 15:25:56
User entered 'None (1)'	System	26 Sep 2020 15:25:56

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96444533-6003-4ab8-b3bf-2885147f0052'	System	26 Sep 2020 15:25:56
User entered '26 Sep 2020 10:25'	System	26 Sep 2020 15:25:56

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 6'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f48e7dc7-a06c-483a-b483-0a6d2368a3a1'	System	27 Sep 2020 16:58:44
User entered 'None (1)'	System	27 Sep 2020 16:58:44

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f48e7dc7-a06c-483a-b483-0a6d2368a3a1'	System	27 Sep 2020 16:58:44
User entered 'No (N)'	System	27 Sep 2020 16:58:44

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:23', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f48e7dc7-a06c-483a-b483-0a6d2368a3a1'	System	27 Sep 2020 16:58:44
User entered 'No (N)'	System	27 Sep 2020 16:58:44

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f48e7dc7-a06c-483a-b483-0a6d2368a3a1'	System	27 Sep 2020 16:58:44
User entered 'None (1)'	System	27 Sep 2020 16:58:44

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:36', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f48e7dc7-a06c-483a-b483-0a6d2368a3a1'	System	27 Sep 2020 16:58:44
User entered '27 Sep 2020 11:58'	System	27 Sep 2020 16:58:44

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 7'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24



US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:24', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:38', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'None (0)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:44', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered 'No (N)'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-21T10:31:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '429ce05f-3de5-497a-a1d5-0696aa1af985'	System	21 Sep 2020 15:31:59
User entered '21 Sep 2020 10:31'	System	21 Sep 2020 15:31:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 10:19'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 12:49'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:00', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:06', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:23', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:28', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:31', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'None (0)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:40', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered 'No (N)'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-22T11:41:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '1548b389-58c1-4d1c-8b21-060bc02d58ec'	System	22 Sep 2020 16:41:59
User entered '22 Sep 2020 11:41'	System	22 Sep 2020 16:41:59

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '21 Sep 2020 13:44'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 2'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:23', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:26', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:33', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:36', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'None (0)'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:40', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered 'No (N)'	System	23 Sep 2020 16:43:53



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-23T11:43:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ab1ed769-cf73-4a23-ac16-ae9146a6c701'	System	23 Sep 2020 16:43:53
User entered '23 Sep 2020 11:43'	System	23 Sep 2020 16:43:53

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 3'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:08', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:12', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:25', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'None (0)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered 'No (N)'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-24T10:58:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'b8c209b2-9542-45ed-873e-5464a3fe0aa8'	System	24 Sep 2020 15:58:43
User entered '24 Sep 2020 10:58'	System	24 Sep 2020 15:58:43

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 4'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:44:55', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:04', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:11', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:14', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'None (0)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered 'No (N)'	System	25 Sep 2020 15:45:50

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-25T10:45:44', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '23ca9e75-2197-4f45-b3fb-4361dd6a7980'	System	25 Sep 2020 15:45:50
User entered '25 Sep 2020 10:45'	System	25 Sep 2020 15:45:50

**US3592232**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:22:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 5'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:25:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:01', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:04', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:10', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:13', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'None (0)'	System	26 Sep 2020 15:26:42



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered 'No (N)'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-26T10:26:36', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '96f841f8-8582-4689-a772-c57ea062c9be'	System	26 Sep 2020 15:26:42
User entered '26 Sep 2020 10:26'	System	26 Sep 2020 15:26:42

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 6'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:55', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:58:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:59:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'None (0)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:59:06', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered 'No (N)'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-09-27T11:59:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'f79cfd1c-d435-4403-94e3-ebab3d703ad5'	System	27 Sep 2020 16:59:21
User entered '27 Sep 2020 11:59'	System	27 Sep 2020 16:59:21

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	21 Sep 2020 15:03:05
User entered 'Day 7'	System	21 Sep 2020 15:03:05



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

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)	25 Feb 2021 10:49:24

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24



US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:03:05

US3592232

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:22:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:03:05

**US3592232**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:54:47

**US3592232**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:35
User entered '29 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:54:47

US3592232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 20:54:47

US3592232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:35
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:54:47

US3592232

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:32:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:55:04

US3592232

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'l'	System	02 Oct 2020 20:55:04



**US3592232**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:20:05

**US3592232**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:07
User entered '6 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 15:20:05

**US3592232**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 15:20:05

US3592232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:07
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 15:20:05

**US3592232**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:20:15

US3592232

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'l'	System	07 Oct 2020 15:20:15

**US3592232**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:16:53

**US3592232**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:34
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 21:16:53



US3592232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 21:16:53

US3592232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:34
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 21:16:53

US3592232

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:33:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:17:37

US3592232

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'I'	System	12 Oct 2020 21:17:37

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:22:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:20:05

US3592232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:00
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:20:05

US3592232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 22:20:05

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:22:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'VISIT3'	System	21 Oct 2020 22:20:05



US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:22:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '08:01'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '19 Oct 2020 08:01'	System	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '97.7' F	(b) (4), (b) (6)	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:22:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:20:39

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:22:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '70'	(b) (4), (b) (6)	21 Oct 2020 22:20:39



US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'bpm'	System	21 Oct 2020 22:20:39

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:22:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '16'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'breaths/min'	System	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '122'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:33
User entered '63'	(b) (4), (b) (6)	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'mmHg'	System	21 Oct 2020 22:20:39

US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33



US3592232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33

US3592232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:20:55

US3592232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:38
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:20:55

US3592232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:21:08

US3592232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:42
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:21:08

**US3592232**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:22:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:42
User entered '08:13'	(b) (4), (b) (6)	21 Oct 2020 22:21:08

US3592232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered '19 Oct 2020 08:13'	System	21 Oct 2020 22:21:08

US3592232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:21:12



US3592232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'I'	System	21 Oct 2020 22:21:12

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 64'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-21T10:31:42', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bd5b747f-bf1b-45fe-8fb9-2630104c4a87'	System	21 Oct 2020 15:32:28
User entered 'No (N)'	System	21 Oct 2020 15:32:28

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

Have you been exposed to someone with 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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-21T10:31:45', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bd5b747f-bf1b-45fe-8fb9-2630104c4a87'	System	21 Oct 2020 15:32:28
User entered 'No (N)'	System	21 Oct 2020 15:32:28

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-21T10:31:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bd5b747f-bf1b-45fe-8fb9-2630104c4a87'	System	21 Oct 2020 15:32:28
User entered '21 Oct 2020 10:31:58'	System	21 Oct 2020 15:32:28

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 71'	System	20 Aug 2020 17:29:10



US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-28T07:53:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4cbdcfbe-3bd3-4cd8-9fdd-1047f254617c'	System	28 Oct 2020 12:53:20
User entered 'No (N)'	System	28 Oct 2020 12:53:20

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

Have you been exposed to someone with 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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-28T07:53:08', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4cbdcfbe-3bd3-4cd8-9fdd-1047f254617c'	System	28 Oct 2020 12:53:20
User entered 'No (N)'	System	28 Oct 2020 12:53:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-10-28T07:53:14', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4cbdcfbe-3bd3-4cd8-9fdd-1047f254617c'	System	28 Oct 2020 12:53:20
User entered '28 Oct 2020 07:53:14'	System	28 Oct 2020 12:53:20

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:29:10

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 78'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-05T13:40:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ccc7d2f-a16e-4119-980c-465b838ccb97'	System	05 Nov 2020 19:41:03
User entered 'No (N)'	System	05 Nov 2020 19:41:03

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

Have you been exposed to someone with 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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-05T13:40:51', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ccc7d2f-a16e-4119-980c-465b838ccb97'	System	05 Nov 2020 19:41:03
User entered 'No (N)'	System	05 Nov 2020 19:41:03



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-05T13:40:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ccc7d2f-a16e-4119-980c-465b838ccb97'	System	05 Nov 2020 19:41:03
User entered '05 Nov 2020 13:40:58'	System	05 Nov 2020 19:41:03

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered 'Day 92'	System	20 Aug 2020 17:29:10

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-18T15:48:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '65d25de0-a5a6-4c4b-801f-f1f9758d1ce9'	System	18 Nov 2020 21:48:59
User entered 'No (N)'	System	18 Nov 2020 21:48:59

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

Have you been exposed to someone with 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)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-18T15:48:44', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '65d25de0-a5a6-4c4b-801f-f1f9758d1ce9'	System	18 Nov 2020 21:48:59
User entered 'No (N)'	System	18 Nov 2020 21:48:59

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-18T15:48:55', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '65d25de0-a5a6-4c4b-801f-f1f9758d1ce9'	System	18 Nov 2020 21:48:59
User entered '18 Nov 2020 15:48:55'	System	18 Nov 2020 21:48:59

US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:29:10



US3592232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:24
Data entry locked.	System	20 Aug 2020 17:29:10
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:29:10

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2020-11-28T09:03:03', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ee1b0b9-e6f6-4a05-a602-b66890a67365'	System	28 Nov 2020 15:03:18
User entered 'No (N)'	System	28 Nov 2020 15:03:18

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2020-11-28T09:03:07', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ee1b0b9-e6f6-4a05-a602-b66890a67365'	System	28 Nov 2020 15:03:18
User entered 'No (N)'	System	28 Nov 2020 15:03:18

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-11-28T09:03:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '2ee1b0b9-e6f6-4a05-a602-b66890a67365'	System	28 Nov 2020 15:03:18
User entered '28 Nov 2020 09:03:15'	System	28 Nov 2020 15:03:18



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2020-12-05T08:59:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd097d9ba-5b75-4d64-baa8-62e78062795d'	System	05 Dec 2020 15:00:00
User entered 'No (N)'	System	05 Dec 2020 15:00:00

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2020-12-05T08:59:52', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd097d9ba-5b75-4d64-baa8-62e78062795d'	System	05 Dec 2020 15:00:00
User entered 'No (N)'	System	05 Dec 2020 15:00:00

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-12-05T08:59:58', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'd097d9ba-5b75-4d64-baa8-62e78062795d'	System	05 Dec 2020 15:00:00
User entered '05 Dec 2020 08:59:58'	System	05 Dec 2020 15:00:00

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2020-12-15T17:05:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '096e98ac-efed-49ad-9f54-82e07b2dcc4f'	System	15 Dec 2020 23:05:49
User entered 'No (N)'	System	15 Dec 2020 23:05:49

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2020-12-15T17:05:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '096e98ac-efed-49ad-9f54-82e07b2dcc4f'	System	15 Dec 2020 23:05:49
User entered 'No (N)'	System	15 Dec 2020 23:05:49

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-12-15T17:05:46', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '096e98ac-efed-49ad-9f54-82e07b2dcc4f' User entered '15 Dec 2020 17:05:46'	System	15 Dec 2020 23:05:49
	System	15 Dec 2020 23:05:49

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2020-12-29T10:39:53', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7693cc-4a3e-4e52-ab9e-53452415208a'	System	29 Dec 2020 16:40:12
User entered 'No (N)'	System	29 Dec 2020 16:40:12

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2020-12-29T10:39:56', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7693cc-4a3e-4e52-ab9e-53452415208a'	System	29 Dec 2020 16:40:12
User entered 'No (N)'	System	29 Dec 2020 16:40:12

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2020-12-29T10:40:08', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'dd7693cc-4a3e-4e52-ab9e-53452415208a'	System	29 Dec 2020 16:40:12
User entered '29 Dec 2020 10:40:08'	System	29 Dec 2020 16:40:12

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-01-02T08:28:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15effb7a-1940-4d9e-b669-2d43dc6da42f'	System	02 Jan 2021 14:28:32
User entered 'No (N)'	System	02 Jan 2021 14:28:32

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-01-02T08:28:24', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15effb7a-1940-4d9e-b669-2d43dc6da42f'	System	02 Jan 2021 14:28:32
User entered 'No (N)'	System	02 Jan 2021 14:28:32

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-01-02T08:28:28', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '15effb7a-1940-4d9e-b669-2d43dc6da42f'	System	02 Jan 2021 14:28:32
User entered '02 Jan 2021 08:28:28'	System	02 Jan 2021 14:28:32

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-01-09T08:32:24', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c5528273-d5f4-4558-835f-d3c005aef42f'	System	09 Jan 2021 14:32:38
User entered 'No (N)'	System	09 Jan 2021 14:32:38

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-01-09T08:32:30', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c5528273-d5f4-4558-835f-d3c005aef42f'	System	09 Jan 2021 14:32:38
User entered 'No (N)'	System	09 Jan 2021 14:32:38



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-01-09T08:32:35', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c5528273-d5f4-4558-835f-d3c005aef42f' User entered '09 Jan 2021 08:32:35'	System	09 Jan 2021 14:32:38

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-01-16T07:16:11', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '477a4f1e-a7cd-4043-9b00-8121e479a98d'	System	16 Jan 2021 13:16:26
User entered 'No (N)'	System	16 Jan 2021 13:16:26

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-01-16T07:16:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '477a4f1e-a7cd-4043-9b00-8121e479a98d'	System	16 Jan 2021 13:16:26
User entered 'No (N)'	System	16 Jan 2021 13:16:26

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-01-16T07:16:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '477a4f1e-a7cd-4043-9b00-8121e479a98d' User entered '16 Jan 2021 07:16:22'	System	16 Jan 2021 13:16:26
	System	16 Jan 2021 13:16:26

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-01-23T05:30:21', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '668a9288-bb7f-4608-b0c0-0841f5a85556'	System	23 Jan 2021 11:30:40
User entered 'No (N)'	System	23 Jan 2021 11:30:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-01-23T05:30:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '668a9288-bb7f-4608-b0c0-0841f5a85556'	System	23 Jan 2021 11:30:40
User entered 'No (N)'	System	23 Jan 2021 11:30:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-01-23T05:30:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '668a9288-bb7f-4608-b0c0-0841f5a85556'	System	23 Jan 2021 11:30:40
User entered '23 Jan 2021 05:30:37'	System	23 Jan 2021 11:30:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-01-30T05:37:21', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c22e72ee-4642-4eaf-9d10-dff95f7ef2a9'	System	30 Jan 2021 11:37:40
User entered 'No (N)'	System	30 Jan 2021 11:37:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-01-30T05:37:25', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c22e72ee-4642-4eaf-9d10-dff95f7ef2a9'	System	30 Jan 2021 11:37:40
User entered 'No (N)'	System	30 Jan 2021 11:37:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-01-30T05:37:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c22e72ee-4642-4eaf-9d10-dff95f7ef2a9'	System	30 Jan 2021 11:37:40
User entered '30 Jan 2021 05:37:37'	System	30 Jan 2021 11:37:40

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-02-06T10:29:13', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e957ac01-abc4-49c0-a46c-4f2b408567ef'	System	06 Feb 2021 16:29:26
User entered 'No (N)'	System	06 Feb 2021 16:29:26

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-02-06T10:29:17', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e957ac01-abc4-49c0-a46c-4f2b408567ef'	System	06 Feb 2021 16:29:26
User entered 'No (N)'	System	06 Feb 2021 16:29:26



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-06T10:29:24', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'e957ac01-abc4-49c0-a46c-4f2b408567ef' User entered '06 Feb 2021 10:29:24'	System	06 Feb 2021 16:29:26
	System	06 Feb 2021 16:29:26

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-02-13T06:31:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9222fab9-af1b-4bdb-a90d-28fdd3e113f5'	System	13 Feb 2021 12:32:08
User entered 'No (N)'	System	13 Feb 2021 12:32:08

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-02-13T06:31:54', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9222fab9-af1b-4bdb-a90d-28fdd3e113f5'	System	13 Feb 2021 12:32:08
User entered 'No (N)'	System	13 Feb 2021 12:32:08

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-13T06:32:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '9222fab9-af1b-4bdb-a90d-28fdd3e113f5'	System	13 Feb 2021 12:32:08
User entered '13 Feb 2021 06:32:02'	System	13 Feb 2021 12:32:08

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-02-20T08:27:46', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82349f26-be8f-4bbb-b3b5-7c497910ec37'	System	20 Feb 2021 14:27:56
User entered 'No (N)'	System	20 Feb 2021 14:27:56

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-02-20T08:27:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82349f26-be8f-4bbb-b3b5-7c497910ec37'	System	20 Feb 2021 14:27:56
User entered 'No (N)'	System	20 Feb 2021 14:27:56

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-20T08:27:54', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82349f26-be8f-4bbb-b3b5-7c497910ec37'	System	20 Feb 2021 14:27:56
User entered '20 Feb 2021 08:27:54'	System	20 Feb 2021 14:27:56

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-02-27T09:23:02', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c96cdd5b-eb2a-4707-9329-4ef1ca06a798'	System	27 Feb 2021 15:23:17
User entered 'No (N)'	System	27 Feb 2021 15:23:17

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-02-27T09:23:08', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c96cdd5b-eb2a-4707-9329-4ef1ca06a798'	System	27 Feb 2021 15:23:17
User entered 'No (N)'	System	27 Feb 2021 15:23:17

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-27T09:23:15', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'c96cdd5b-eb2a-4707-9329-4ef1ca06a798'	System	27 Feb 2021 15:23:17
User entered '27 Feb 2021 09:23:15'	System	27 Feb 2021 15:23:17

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-03-06T07:29:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ca321469-be7d-4882-a794-499b052f46ad'	System	06 Mar 2021 13:29:53
User entered 'No (N)'	System	06 Mar 2021 13:29:53

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-03-06T07:29:43', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ca321469-be7d-4882-a794-499b052f46ad'	System	06 Mar 2021 13:29:53
User entered 'No (N)'	System	06 Mar 2021 13:29:53



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-03-06T07:29:50', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'ca321469-be7d-4882-a794-499b052f46ad' User entered '06 Mar 2021 07:29:50'	System	06 Mar 2021 13:29:53
	System	06 Mar 2021 13:29:53

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-03-13T09:03:32', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '25f81cf2-6cc0-40ae-b684-fe1361be0c9f' User entered 'No (N)'	System	13 Mar 2021 15:03:44

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-03-13T09:03:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '25f81cf2-6cc0-40ae-b684-fe1361be0c9f'	System	13 Mar 2021 15:03:44
User entered 'No (N)'	System	13 Mar 2021 15:03:44

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-03-13T09:03:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '25f81cf2-6cc0-40ae-b684-fe1361be0c9f' User entered '13 Mar 2021 09:03:41'	System	13 Mar 2021 15:03:44
	System	13 Mar 2021 15:03:44

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-03-20T06:30:29', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bcfd8c3b-71b5-4199-885f-78873c38912f'	System	20 Mar 2021 11:30:54
User entered 'No (N)'	System	20 Mar 2021 11:30:54

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-03-20T06:30:37', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bcfd8c3b-71b5-4199-885f-78873c38912f'	System	20 Mar 2021 11:30:54
User entered 'No (N)'	System	20 Mar 2021 11:30:54

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-03-20T06:30:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: 'bcfd8c3b-71b5-4199-885f-78873c38912f' User entered '20 Mar 2021 06:30:49'	System	20 Mar 2021 11:30:54
	System	20 Mar 2021 11:30:54

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-03-27T16:38:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82a66f5b-4e50-444d-bb9b-044d4881eb40'	System	27 Mar 2021 21:38:46
User entered 'No (N)'	System	27 Mar 2021 21:38:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-03-27T16:38:32', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82a66f5b-4e50-444d-bb9b-044d4881eb40'	System	27 Mar 2021 21:38:46
User entered 'No (N)'	System	27 Mar 2021 21:38:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-03-27T16:38:42', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '82a66f5b-4e50-444d-bb9b-044d4881eb40'	System	27 Mar 2021 21:38:46
User entered '27 Mar 2021 16:38:42'	System	27 Mar 2021 21:38:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-04-03T05:50:44', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '20dbbf00-fa96-4d74-ba12-ad8865c50484'	System	03 Apr 2021 10:50:59
User entered 'No (N)'	System	03 Apr 2021 10:50:59

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-04-03T05:50:48', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '20dbbf00-fa96-4d74-ba12-ad8865c50484'	System	03 Apr 2021 10:50:59
User entered 'No (N)'	System	03 Apr 2021 10:50:59



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-04-03T05:50:57', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '20dbbf00-fa96-4d74-ba12-ad8865c50484'	System	03 Apr 2021 10:50:59
User entered '03 Apr 2021 05:50:57'	System	03 Apr 2021 10:50:59

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-04-10T07:41:14', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0177dc8d-3ef7-403c-9b37-7725a48a10b5'	System	10 Apr 2021 12:41:46
User entered 'No (N)'	System	10 Apr 2021 12:41:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-04-10T07:41:20', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0177dc8d-3ef7-403c-9b37-7725a48a10b5'	System	10 Apr 2021 12:41:46
User entered 'No (N)'	System	10 Apr 2021 12:41:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-04-10T07:41:41', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '0177dc8d-3ef7-403c-9b37-7725a48a10b5'	System	10 Apr 2021 12:41:46
User entered '10 Apr 2021 07:41:41'	System	10 Apr 2021 12:41:46

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-04-17T05:42:19', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4583c567-2d6d-47fa-ba77-f0946bb8f674'	System	17 Apr 2021 10:42:36
User entered 'No (N)'	System	17 Apr 2021 10:42:36

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-04-17T05:42:23', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4583c567-2d6d-47fa-ba77-f0946bb8f674'	System	17 Apr 2021 10:42:36
User entered 'No (N)'	System	17 Apr 2021 10:42:36

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-04-17T05:42:32', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '4583c567-2d6d-47fa-ba77-f0946bb8f674'	System	17 Apr 2021 10:42:36
User entered '17 Apr 2021 05:42:32'	System	17 Apr 2021 10:42:36

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[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 (35f338edb8e68eca)', Time: '2021-05-01T06:25:49', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '496b0103-024e-4223-acf2-304d07c066b1'	System	01 May 2021 11:26:11
User entered 'No (N)'	System	01 May 2021 11:26:11

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Have you been exposed to someone with 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 (35f338edb8e68eca)', Time: '2021-05-01T06:25:56', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '496b0103-024e-4223-acf2-304d07c066b1'	System	01 May 2021 11:26:11
User entered 'No (N)'	System	01 May 2021 11:26:11

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-05-01T06:26:05', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '496b0103-024e-4223-acf2-304d07c066b1'	System	01 May 2021 11:26:11
User entered '01 May 2021 06:26:05'	System	01 May 2021 11:26:11

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:46:20



**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:46:20

**US3592232**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:22:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:46:20
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:46:20

US3592232

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:22:05**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:27:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-27T09:23:22', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '72fd090f-3c2b-459f-aba1-a14a26c0b604'	System	27 Feb 2021 15:23:34
User entered 'No (N)'	System	27 Feb 2021 15:23:34



US3592232

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:22:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:27:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f338edb8e68eca)', Time: '2021-02-27T09:23:27', User OID: 'PatientReportedOutcome (US3592232)', ODM File OID: '72fd090f-3c2b-459f-aba1-a14a26c0b604'	System	27 Feb 2021 15:23:34
User entered '27 Feb 2021 09:23:27'	System	27 Feb 2021 15:23:34

**US3592232**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:30:51

**US3592232**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:53
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 18:30:51

US3592232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 18:30:51

US3592232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:34:53
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:30:51

US3592232

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:58:47
User closed query 'Please enter Safety Call Day 119 data as per source on file.' (Site from CRA).	(b) (4)	22 Jan 2021 16:41:56
Query 'Please enter Safety Call Day 119 data as per source on file.' answered with 'Data entered correctly' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 21:29:08
User opened query 'Please enter Safety Call Day 119 data as per source on file.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 19:36:01
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:35:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:30:56

US3592232

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:24:33
User entered 'l'	System	17 Nov 2020 18:30:56

US3592232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:26:21



US3592232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	21 Jan 2021 21:28:41
User entered '20 Dec 2020' reason for change: Data Entry Error	System	21 Jan 2021 21:28:41
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 21:26:21
User entered '19 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 21:26:21

US3592232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:26:21

US3592232

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered empty.	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:26:21

US3592232

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:29:21

**US3592232**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User entered 'l'	System	21 Jan 2021 21:29:21

US3592232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:29:53

US3592232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:29:53

US3592232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:29:53



US3592232

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered empty.	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:29:53

US3592232

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:29:58

**US3592232**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User entered 'l'	System	21 Jan 2021 21:29:58

US3592232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:33:00

US3592232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:33:00

US3592232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:33:00

US3592232

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:33:00

US3592232

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:33:07



**US3592232**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:03
User entered 'l'	System	20 Feb 2021 19:33:07

US3592232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:29:56

US3592232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:29:56

US3592232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:29:56

US3592232

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'VISIT4'	System	18 Mar 2021 20:29:56

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '08:15'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11



US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered '17 Mar 2021 08:15'	System	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '70'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'bpm'	System	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'breaths/min'	System	03 Apr 2021 15:52:11



US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '105'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'mmHg'	System	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	03 Apr 2021 15:52:24
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	03 Apr 2021 15:52:24
User entered '63' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Apr 2021 15:52:24
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Apr 2021 15:52:11
User entered '53'	(b) (4), (b) (6)	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'mmHg'	System	03 Apr 2021 15:52:11

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20

US3592232

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20

US3592232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:17

US3592232

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:17



US3592232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:29

US3592232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:29

US3592232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered '08:28'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:29

US3592232

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered '17 Mar 2021 08:28'	System	18 Mar 2021 20:30:29

US3592232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:30:34

US3592232

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:20
User entered 'I'	System	18 Mar 2021 20:30:34

**US3592232**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	21 Apr 2021 15:32:08

US3592232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '19 Apr 2021'	(b) (4) (D) (4), (D) (6)	21 Apr 2021 15:32:08



**US3592232**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:22:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (D) (4), (D) (6)	21 Apr 2021 15:32:08

US3592232

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered empty.	(b) (4) (D) (4), (D) (6)	21 Apr 2021 15:32:08

US3592232

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	21 Apr 2021 15:32:15

**US3592232**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Apr 2021 15:32:15

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:12

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:12

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:05

[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 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:12

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:22:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 21:24:12



US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:22:05**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:55:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:59:34

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User closed query 'Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 06:39:54
Query 'Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:55:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:55:38
User opened query 'Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 04:13:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:59:34

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24



US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:22:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User entered empty.	System	21 Jan 2021 21:24:24

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:22:05**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User entered empty.	System	21 Jan 2021 21:24:24

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:37

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:37

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '08:35'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:37

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:22:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User entered '15 Jan 2021 08:35'	System	21 Jan 2021 21:24:37

US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:53



US3592232

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:53

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:22:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
User entered '08:32'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:24:53

**US3592232**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:22:05**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:15
User entered '15 Jan 2021 08:32'	System	21 Jan 2021 21:24:53

US3592232

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:22:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:11:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:16:22

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
Query 'Please correct site number as the site is US359.' canceled (DM from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 04:16:37
User opened query 'Please correct site number as the site is US359.' (DM from CRA).	(b) (4), (b) (6)	17 Sep 2020 16:12:02
Query 'Please remove/correct, not of this site. Should be US359...' canceled (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 14:44:36
User opened query 'Please remove/correct, not of this site. Should be US359...' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 14:40:07
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 14:39:53
User entered	(b) (4), (b) (6)	30 Aug 2020 14:45:49
'USA-US103-2020-mRNA-1273-P301000001'	System	30 Aug 2020 14:45:42
User entered 'New'	(b) (4), (b) (6)	30 Aug 2020 14:45:42

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femoral neck fracture, LLT: Femoral neck fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:01:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:01:54
Data point term sent to Coder	System	18 Sep 2020 17:55:59
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 17:55:29
Coding entries removed.	(b) (4), (b) (6)	18 Sep 2020 17:55:29
User entered 'RIGHT subcapital femoral neck fracture, displaced garden III' reason for change:	(b) (4), (b) (6)	18 Sep 2020 17:55:29
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:05
User closed query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	13 Sep 2020 01:02:38
Query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' answered with 'Fall was due to subject stepping and tripping over a gate in her home, not due to a medically related reason.' (Site from Safety).	Diandra Henriques (b) (4) (b) (4)	11 Sep 2020 15:40:44
User opened query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:58:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:53:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 14:53:45
Data point term sent to Coder	System	28 Aug 2020 14:52:36
User entered 'Right hip fracture'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:12:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:13:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53



US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:18:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 15:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 15:41:56
User entered 'No (N)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	11 Sep 2020 15:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 14:51:53
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:25
User entered '25 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:38:30
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:11:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:18:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:38:33
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:11:47
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:18:31
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:33
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the end date, when available. Please do not answer this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:31:44
User opened query 'PV query: Please provide the end date, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:54:47
User entered empty.	System	28 Aug 2020 14:51:53



US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:36
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:18:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Aug 2020 14:52:45
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Aug 2020 14:51:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:18:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:43
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:45
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).	(b) (4), (b) (6)	31 Aug 2020 17:41:33
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 'Subject is still in the hospital at this time.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 14:53:24
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Aug 2020 14:52:45
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		28 Aug 2020 14:52:45
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	28 Aug 2020 14:52:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 14:52:45
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Aug 2020 14:51:53
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:49
User entered '25 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:38:39
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:57:51
Query 'PV query: Please provide the discharge date, when available.' answered with 'Discharge date provided.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 17:56:19
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 17:55:29
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 17:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:18:51
Query 'Per ETRTR: Please provide the event end date, when available. Please leave this query open until the response can be updated.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:50:38
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:55:44
User opened query 'Per ETRTR: Please provide the event end date, when available. Please leave this query open until the response can be updated.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 16:04:45
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:38:41
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Sep 2020 17:55:29
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		18 Sep 2020 17:55:29
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 17:55:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 17:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:18:55
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	28 Aug 2020 14:51:53
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:18:57
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:03
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:05
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:07
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:19:12
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:19:14
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:38:46
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:32:21
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'updated; conmeds and conprocedure already entered.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:52:41
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
User entered '0' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(D) (4), (D) (6)	22 Oct 2020 08:43:54
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:19:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Aug 2020 14:56:28
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 14:56:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Aug 2020 14:51:53

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:38:50
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
User entered '1' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
DataPoint Verified.	(D) (4), (D) (6)	17 Sep 2020 16:19:20
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:38:52
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
User entered '1' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 21:49:54
DataPoint Verified.	(D) (4), (D) (6)	17 Sep 2020 16:19:22
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

US3592232

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:38:54
User closed query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:32:41
Query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:12:03
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:11:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:11:47
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:19:24
User opened query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:55:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:19:28
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:39:02
Query 'PV Query: Please provide any additional treatment given for the event (i.e. pain medication, PT/OT). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:49:01
Query 'PV Query: Please provide any diagnostic test results (i.e. hip x-ray) used to diagnose event.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 18:40:00
User entered 'SUBJECT WAS CONTACTED ON 27AUG2020 FOR SCHEDULED DAY 8 SAFETY PHONE CALL. SHE REPORTED SHE SUSTAINED A FALL ON 25AUG2020 WHICH RESULTED IN A RIGHT HIP FRACTURE. SHE HAD SURGERY ON 26AUG2020 WHERE A PLATE AND PINS/SCREWS WERE TO REPAIR THE FRACTURE. AT THE TIME OF THE CALL SHE WAS STILL IN THE HOSPITAL.	(b) (4), (b) (6)	18 Sep 2020 19:59:52
RECORDS RECEIVED. x-ray right hip, right femur 25August2020 showed subcapital fracture of the right proximal femur/hip. SUBJECT UNDERWENT ORIF OF THE RIGHT FEMORAL NECK WITH NO COMPLICATIONS. TO BE TOE TOUCH WEIGHTBEARING. SUBJECT CONFIRMS TRIPPED OVER A BABY GATE IN HER HOME. DISCHARGED HOME WITH FOUR WHEEL WALKER FOR MOBILIZATION.' reason for change: Data Entry Error		
DataPoint Un-verified.	(b) (4), (b) (6)	18 Sep 2020 17:55:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS CONTACTED ON 27AUG2020 FOR SCHEDULED DAY 8 SAFETY PHONE CALL. SHE REPORTED SHE SUSTAINED A FALL ON 25AUG2020 WHICH RESULTED IN A RIGHT HIP FRACTURE. SHE HAD SURGERY ON 26AUG2020 WHERE A PLATE AND PINS/SCREWS WERE TO REPAIR THE FRACTURE. AT THE TIME OF THE CALL SHE WAS STILL IN THE HOSPITAL.  Records received. Subject underwent ORIF of the right femoral neck with no complications. To be toe touch weightbearing. Subject confirms tripped over a baby gate in her home. Discharged home with four wheel walker for mobilization.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 17:55:29
	(b) (4), (b) (6)	17 Sep 2020 16:19:37
User closed query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, poor vision, etc.)' (Site from Safety).	(b) (4), (b) (6)	13 Sep 2020 01:02:59
Query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, poor vision, etc.)' answered with 'Subject accidentally fell while stepping and tripping over a gate that was in her home.' (Site from Safety).	Diandra Henriques (b) (4) (b) (4)	11 Sep 2020 15:42:57
Query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:51:27
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:51:25
User opened query 'PV Query: What was the reason for the fall? (i.e. accidental, dizziness, poor vision, etc.)' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:57:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional treatment given for the event (i.e. pain medication, PT/OT). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:56:50
User opened query 'PV Query: Please provide any diagnostic test results (i.e. hip x-ray) used to diagnose event.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 19:56:18
User opened query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 16:40:23
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Sep 2020 16:40:09
User entered 'Subject was contacted on 27Aug2020 for scheduled Day 8 safety phone call. She reported she sustained a fall on 25Aug2020 which resulted in a right hip fracture. She had surgery on 26Aug2020 where a plate and pins/screws were to repair the fracture. At the time of the call she was still in the hospital.'	(b) (4), (b) (6)	28 Aug 2020 14:51:53



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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	28 Aug 2020 14:51:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 14:51:53

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 14:51:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:49:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:49:30
Data point term sent to Coder	System	07 Oct 2020 16:43:36
User entered 'right hip pain'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '25 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User entered empty.	System	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 09:42:48
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:13:21
Un-reviewed for Data Management.	(b) (4), (b) (6)	21 Jan 2021 21:13:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:13:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:13:04
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:49:17
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 09:42:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'data updated' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 21:13:10
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	21 Jan 2021 21:13:04
Un-reviewed for Data Management.	(b) (4), (b) (6)	21 Jan 2021 21:13:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:13:04
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:13:04
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User entered empty.	System	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:47:23
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Confirm severity of grade 4 is correct as entered due to use of Fentanyl. Not serious adverse event.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 22:05:29
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		07 Oct 2020 16:43:31
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31



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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 16:43:31



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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per CDM: End date has been provided. Please re-asses the outcome of the event.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 06:57:44
Query 'Per CDM: End date has been provided. Please re-asses the outcome of the event.' answered with 'outcome updated' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	25 Feb 2021 13:38:25
Un-reviewed for Data Management.	Diandra Henriques (b) (4) (b) (4)	25 Feb 2021 13:38:17
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	25 Feb 2021 13:38:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Diandra Henriques (b) (4) (b) (4)	25 Feb 2021 13:38:17
User opened query 'Per CDM: End date has been provided. Please re-asses the outcome of the event.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:43:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
Reviewed for Data Management.	(b) (4), (b) (6)	29 Oct 2020 09:37:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User entered '0'	System	07 Oct 2020 16:43:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10
User entered 'I'	System	07 Oct 2020 16:43:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'For coding purposes, please split CHEST WALL PAIN, MUSCULOSKELETAL, SECONDARY TO FALL into separate entries. 1. CHEST WALL PAIN, MUSCULOSKELETAL, [SECONDARY TO FALL] and 2. FALL' (Site from Coder).	(b) (4) (b) (4), (b) (6)	14 Mar 2021 17:04:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 10:36:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 10:36:16
Data point term sent to Coder	System	21 Jan 2021 21:10:29
Query 'For coding purposes, please split CHEST WALL PAIN, MUSCULOSKELETAL, SECONDARY TO FALL into separate entries. 1. CHEST WALL PAIN, MUSCULOSKELETAL, [SECONDARY TO FALL] and 2. FALL' answered with 'data updated' (Site from Coder).	(b) (4), (b) (6)	21 Jan 2021 21:09:42
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:09:37
Coding entries removed.	(b) (4), (b) (6)	21 Jan 2021 21:09:37
User entered 'CHEST WALL PAIN, MUSCULOSKELETAL, {SECONDARY TO FALL}' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:09:37
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
User opened query 'For coding purposes, please split CHEST WALL PAIN, MUSCULOSKELETAL, SECONDARY TO FALL into separate entries. 1. CHEST WALL PAIN, MUSCULOSKELETAL, [SECONDARY TO FALL] and 2. FALL' (Site from Coder).	(b) (4), (b) (6)	28 Nov 2020 17:28:42

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 19:05:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 19:05:08
Data point term sent to Coder	System	24 Nov 2020 18:42:51
Query 'CDM Coding, please split the AE into two separate records, as 'CHEST WALL PAIN, MUSCULOSKELETAL' and 'FALL' reporting each term separately with all relevant information e.g. start and stop dates etc' canceled (Site from System).	Coder Import (b) (4)	24 Nov 2020 18:41:55
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST WALL PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	13 Nov 2020 06:45:12
' (Site from DM).		
User opened query 'CDM Coding, please split the AE into two separate records, as 'CHEST WALL PAIN, MUSCULOSKELETAL' and 'FALL' reporting each term separately with all relevant information e.g. start and stop dates etc' (Site from System).	Coder Import (b) (4)	11 Nov 2020 04:05:44
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST WALL PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Diandra Henriques (b) (4)	10 Nov 2020 22:02:06
' answered with 'Per medical records, subject reported "some pain across her chest when she takes a deep breath," was coded as "chest wall pain secondary to fall."' (Site from DM).		
Data point term sent to Coder	System	10 Nov 2020 22:01:49

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Diandra Henriques (b) (4)	10 Nov 2020 22:00:59
User entered 'CHEST WALL PAIN, MUSCULOSKELETAL, SECONDARY TO FALL' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST WALL PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Diandra Henriques (b) (4)	10 Nov 2020 22:00:59
' (Site from DM).	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	(b) (4), (b) (6)	02 Nov 2020 12:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:52:12
Data point term sent to Coder	(b) (4)	
User entered 'chest wall pain'	Coder Import (b) (4)	07 Oct 2020 16:52:12
	System	07 Oct 2020 16:46:40
	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '25 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52



US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User entered empty.	System	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 09:44:02
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:12:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:11:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:11:54
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:49:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 09:44:04
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'data updated' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 21:12:06
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	21 Jan 2021 21:11:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:11:54
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:11:54
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User entered empty.	System	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52



US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'l'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:12:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:12:13
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 16:45:52



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:22:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User entered '0'	System	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14
User entered 'I'	System	07 Oct 2020 16:45:52

US3592232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:14

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User closed query 'Per DM CLR: Please update the condition to confirm if the NODULE was benign or cancerous, as well as location. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:30:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:44:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:44:41
Data point term sent to Coder	System	10 Nov 2020 22:03:55
Query 'Per DM CLR: Please update the condition to confirm if the NODULE was benign or cancerous, as well as location. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'term updated' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:03:26
Coding entries removed.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:03:14
User entered 'THYROID NODULE, RIGHT, BENIGN' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:03:14
User opened query 'Per DM CLR: Please update the condition to confirm if the NODULE was benign or cancerous, as well as location. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:46:59
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:53:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	07 Oct 2020 16:53:26
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 16:47:41
User entered 'thyroid nodule'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '25 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 16:46:46

US3592232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	07 Oct 2020 16:46:46



US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: White blood cell disorders, HLT: Leukocytoses NEC, PT: Leukocytosis, LLT: Leukocytosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:24:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:24:15
Data point term sent to Coder	System	07 Oct 2020 16:48:44
User entered 'afebrile leukocytosis'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '27 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 16:48:42
User entered empty; reason for change New Information	(b) (4), (b) (6)	07 Oct 2020 16:48:42
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 16:48:16
User entered '08:59'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User entered empty.	System	07 Oct 2020 16:48:42
User entered '27 Aug 2020 08:59'	System	07 Oct 2020 16:48:16



US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '28 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 16:48:42
User entered empty; reason for change New Information	(b) (4), (b) (6)	07 Oct 2020 16:48:42
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 16:48:16
User entered '05:37'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User entered empty.	System	07 Oct 2020 16:48:42
User entered '28 Aug 2020 05:37'	System	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16



US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16



US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'l'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 16:48:16

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:22:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User entered '0'	System	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21
User entered 'I'	System	07 Oct 2020 16:48:16

US3592232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:22:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:21

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:01
Data point term sent to Coder	System	07 Oct 2020 16:50:49
User entered 'urinary retention'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10



US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '27 Aug 2020'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10



US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10



US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:40:15
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'l'	(b) (4), (b) (6)	07 Oct 2020 16:50:10



US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:40:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:22:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 16:50:10

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 16:50:10

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Jan 2021 21:12:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 21:12:08
Data point term sent to Coder	System	21 Jan 2021 21:11:29
User entered 'Fall'	(b) (4), (b) (6)	21 Jan 2021 21:11:26



US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User entered empty.	System	21 Jan 2021 21:11:26

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26



US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User entered empty.	System	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26



US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26



**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'None (NONE)'	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'l'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:11:26

**US3592232**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (D) (4), (D) (6)	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User entered '0'	System	21 Jan 2021 21:11:26



US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28
User entered '0'	System	21 Jan 2021 21:11:26

US3592232

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:22:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:47:28

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 08:22:05**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:25:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:31:54

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:27:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:34:17
Data point term sent to Coder	System	21 Aug 2020 14:33:40
User entered 'alendronate'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:44
User entered 'osteoporosis'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:48
User entered '70'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:49
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:27:54
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:56
User entered 'every week (QS)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:57
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:27:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:01
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:03
User entered 'un Jul 2019'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:04
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:10
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:33:20

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:11
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 14:33:20

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	21 Aug 2020 14:33:20

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:24
Data point term sent to Coder	System	21 Aug 2020 14:35:46
User entered 'amlodipine'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'hypertension'	(b) (4), (b) (6)	21 Aug 2020 14:35:07



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:37:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'start date of medical history updated ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:12:51
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:23:43
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 08:27:18
User entered 'un Oct 2007'	(b) (4), (b) (6)	17 Sep 2020 16:28:35
	(b) (4), (b) (6)	21 Aug 2020 14:35:07



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:35:07

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:35:07

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:37:00
User entered '2'	System	21 Aug 2020 14:35:07

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 14:35:07

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:35:07

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:49
User entered 'lisinopril'	(b) (4), (b) (6)	21 Aug 2020 14:36:40



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'hypertension'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'start date of medical history updated ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:13:07
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:23:50
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 08:27:32
User entered 'un Oct 2007'	(b) (4), (b) (6)	17 Sep 2020 16:28:35
	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:36:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:36:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 14:36:40



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:36:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:40:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:40:22
Data point term sent to Coder	System	21 Aug 2020 14:38:55
User entered 'omeprazole'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'un Apr 2018'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:38:42

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:38:42



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 14:38:42

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:38:42

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:41:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:41:52
Data point term sent to Coder	System	21 Aug 2020 14:40:02
User entered 'trazadone'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'anxiety'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '50'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'un UNK 2018'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:40:02

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 14:40:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:40:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
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 D 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:43:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:43:22
Data point term sent to Coder	System	21 Aug 2020 14:42:06
User entered 'vitamin d 3'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:02:29
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:15:58
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:15:46
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:08:20
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'nutritional supplement'	(b) (4), (b) (6)	21 Aug 2020 14:41:38



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:41:05
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:49:33
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 22:00:55
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:00:50
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:00:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:27:56
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:41:14
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:00:50
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:00:50
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'un UNK 2007'	(b) (4), (b) (6)	21 Aug 2020 14:41:38



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:41:38

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:41:38

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 14:41:38

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:41:38

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:05:45
Data point term sent to Coder	System	10 Nov 2020 22:04:58
Coding entries removed.	Diandra Henriques (b) (4)	10 Nov 2020 22:04:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 14:58:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 14:58:37
Data point term sent to Coder	System	04 Sep 2020 14:58:06
User entered 'tylenol'	(b) (4), (b) (6)	04 Sep 2020 14:57:46



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:41:22
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:20:33
Query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'indication updated to match AE' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:04:36
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:04:18
User entered 'RIGHT HIP PAIN' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:04:18
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:18:40
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'pain management'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '325'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'other (OTHER)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'every four hours'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '25 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '28 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 14:57:46

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User entered empty.	System	04 Sep 2020 14:57:46

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User entered empty.	System	04 Sep 2020 14:57:46



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:33
User entered empty.	System	04 Sep 2020 14:57:46

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:06:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:06:52
Data point term sent to Coder Coding entries removed.	System	10 Nov 2020 22:06:00
	Diandra Henriques (b) (4)	10 Nov 2020 22:04:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 15:02:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 15:02:05
Data point term sent to Coder	System	04 Sep 2020 15:00:10
User entered 'acetaminophen'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:41:31
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:21:06
Query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'indication updated to match AE' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:05:03
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:04:59
User entered 'RIGHT HIP PAIN' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Nov 2020 22:04:59
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:19:12
Data hard unlocked.	(b) (4), (b) (6)	26 Oct 2020 18:19:07
Data hard locked.	(b) (4), (b) (6)	26 Oct 2020 18:19:02
DataPoint Verified.	(D) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'pain management'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '500'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:59:52

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '27 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 14:59:52



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 14:59:52

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 14:59:52

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 14:59:52

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:41:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 10:18:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 10:18:26
Data point term sent to Coder	System	21 Oct 2020 22:00:12
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 22:00:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:41:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:41:47
Data point term sent to Coder	System	07 Oct 2020 23:11:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 23:11:04
Coding entries removed.	(b) (4), (b) (6)	07 Oct 2020 23:11:04
User entered 'DOCUSATE SODIUM' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 23:11:04
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 08:13:51

PRODUCTION RELEASE (v12.003  
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US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Sep 2020 08:13:51
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Sep 2020 15:04:20
User entered 'docusal sodium'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:02:45
Query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:17:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:17:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:17:06
User opened query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:05:41
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:13:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	15 Mar 2021 19:38:35
' answered with 'confirm indication is correct as entered this medication was given for SAE during hospital stay. ' (Site from DM).		
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:37:04
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:41:45
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:49:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	21 Oct 2020 22:00:12
' answered with 'indication updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:00:05

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'right subcapital femoral neck fracture, displaced garden III' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:00:05
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'constipation'	(b) (4), (b) (6)	04 Sep 2020 15:03:55



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '100'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:03:55

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:03:55

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:03:55

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '27 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 15:03:55



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:02:51
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:17:34
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:17:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:17:26
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:05:50
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	System	21 Jan 2021 21:17:39
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 21:17:39
DataPoint Un-verified.	System	21 Jan 2021 21:17:26
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:17:26
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 15:04:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 15:04:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:04:18
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 15:03:55
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:03:55

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User entered '2'	System	04 Sep 2020 15:03:55

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User entered 'I'	System	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:36
User entered '804 (804)'	System	04 Sep 2020 15:03:55

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 22:02:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 22:02:46
Data point term sent to Coder	System	21 Oct 2020 22:02:13
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 22:02:01
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 15:08:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 15:08:48
Data point term sent to Coder	System	04 Sep 2020 15:08:26
User entered 'miralax'	(b) (4), (b) (6)	04 Sep 2020 15:07:59



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:02:59
Query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:18:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:18:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:18:05
User opened query 'Per DM CLR: Prophylaxis? = Yes. Please review if this indication should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update the Prophylaxis field as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:06:25
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:13:49
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	15 Mar 2021 19:38:41
' answered with 'confirm indication is correct as entered this medication was given for SAE during hospital stay. ' (Site from DM).		
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:38:42
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:41:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:49:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	21 Oct 2020 22:02:05
' answered with 'done' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:02:01

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'right subcapital femoral neck fracture, displaced garden III' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:02:01
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:57:13
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'constipation'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:13:52
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated dosafe ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 19:38:58
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 19:38:50
User entered '17' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:38:50
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:39:22
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '170'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:38:50
User entered 'g (g)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:38:50
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:07:59



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:07:59

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '27 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:03:02
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:18:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:18:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:18:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:06:11
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:18:05
User entered '3 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:18:05
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:07:59

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User entered 'I'	System	04 Sep 2020 15:07:59



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User entered 'I'	System	04 Sep 2020 15:07:59

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:39
User entered '804 (804)'	System	04 Sep 2020 15:07:59

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
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) (b) (4)	04 Sep 2020 15:10:38
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 Sep 2020 15:10:38
Data point term sent to Coder	System	04 Sep 2020 15:09:29
User entered 'tamsulosin'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:42:21
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:03:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:03:00
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 04:48:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Adverse event added' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 22:03:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:57:23
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'urinary retention'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '.4'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:09:17



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:09:17

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered '27 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:28:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:09:17



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	17 Sep 2020 16:28:35
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:09:17

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 15:09:17

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 15:09:17

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 15:09:17

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:31:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:31:18
Data point term sent to Coder	System	29 Sep 2020 17:28:00
User entered 'apixiban'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'deep vein thrombosis prophylaxis'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered '2.5'	(b) (4), (b) (6)	29 Sep 2020 17:27:40



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:27:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:27:40



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 17:27:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 17:27:40

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 17:27:40

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:27:40

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
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)	29 Sep 2020 22:33:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:33:46
Data point term sent to Coder	System	29 Sep 2020 17:47:59
User entered 'aspirin'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'deep vein thrombosis prophylaxis'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '81'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:47:12

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:47:12



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '1 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 17:47:12

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 17:47:12

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 17:47:12

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 17:47:12

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:47:12



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL CITRATE, PRODUCTSYNONYM: FENTANYL [FENTANYL CITRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:07:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:07:41
Data point term sent to Coder	System	29 Sep 2020 18:06:43
User entered 'fentanyl'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'right hip pain, chest wall pain'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '50'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'ug (ug)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:06:10



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 18:06:10

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '25 Aug 2020'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '25 Aug 2020'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 18:06:10

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User entered empty.	System	29 Sep 2020 18:06:10



US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User entered empty.	System	29 Sep 2020 18:06:10

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:08:44
User entered empty.	System	29 Sep 2020 18:06:10

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:14:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:14:34
Data point term sent to Coder	System	21 Oct 2020 22:07:20
User entered 'nitrofurantoin'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'frequent urinary tract infections'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:07:03



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:07:03

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:07:03

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '25 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:07:03



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:07:03

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User entered '2'	System	21 Oct 2020 22:07:03

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User entered 'I'	System	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:22:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:03
User entered '804 (804)'	System	21 Oct 2020 22:07:03

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 03:41:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 03:41:03
User closed query 'DM-Coding: Please add the active System ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).		10 Nov 2020 21:51:27
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated ' (Site from System).	Diandra Henriques (b) (4)	10 Nov 2020 21:51:27
Data point term sent to Coder	System	10 Nov 2020 21:51:27
User entered 'ANCEF [CEFAZOLIN]' reason for change: Data Entry Error	Diandra Henriques (b) (4)	10 Nov 2020 21:51:15
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	26 Oct 2020 12:26:21
Data point term sent to Coder	System	21 Oct 2020 22:09:21
User entered 'Ancef'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Preoperative - hip surgery'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '3'	(b) (4), (b) (6)	21 Oct 2020 22:09:02



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'g (g)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:09:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '25 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:09:02



**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered '26 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:16
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:09:02

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User entered 'I'	System	21 Oct 2020 22:09:02

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User entered 'I'	System	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:22:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:06
User entered '804 (804)'	System	21 Oct 2020 22:09:02

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
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)	15 Mar 2021 19:24:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 19:24:32
Data point term sent to Coder	System	15 Mar 2021 19:24:11
User entered 'influenza vaccine'	(b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0.5'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:22:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06



US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

**US3592232**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:22:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:22:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:24:06

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:22:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User entered empty.	System	15 Mar 2021 19:24:06

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User entered empty.	System	15 Mar 2021 19:24:06

US3592232

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:22:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:09:10
User entered empty.	System	15 Mar 2021 19:24:06



US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:22:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:43:23
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:10:49
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:31:47
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 17:04:55

US3592232

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:22:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered '26 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:12:11

US3592232

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'right femoral neck open reduction internal fixation'	(b) (4), (b) (6)	21 Oct 2020 22:12:11

US3592232

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Oct 2020 22:12:11

US3592232

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:22:05**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:44:02
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:12:11

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:22:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:51
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered '25 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 22:13:30

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:22:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:51
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'magnetic resonance imaging'	(b) (4), (b) (6)	21 Oct 2020 22:13:30

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:51
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:03:45
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	21 Jan 2021 21:22:03
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:21:59
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	21 Jan 2021 21:21:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:21:46
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:21:46
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:44:02
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:46:52
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Oct 2020 22:13:30



US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:22:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:51
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 21:21:55
User entered 'Fall' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 21:21:55
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'right hip pain'	(b) (4), (b) (6)	21 Oct 2020 22:13:30

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:22:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:55
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered '12 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:14:01

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:22:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:55
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'thyroid sonogram'	(b) (4), (b) (6)	21 Oct 2020 22:14:01

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:22:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:55
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Oct 2020 22:14:01

US3592232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:22:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:55
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:44:02
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:14:01

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42



**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:22:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered '30/Aug/2020 10:46'	System	30 Aug 2020 14:46:22

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:22:05

**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.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'l'	(b) (4), (b) (6)	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42



**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:22:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered '12/Sep/2020 21:02'	System	13 Sep 2020 01:02:02



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:22:05

**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.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
User entered 'l'	(b) (4), (b) (6)	13 Sep 2020 01:02:02

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42



**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22



**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:22:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered '20/Sep/2020 16:58'	System	20 Sep 2020 20:58:18

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:22:05

**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.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:32:53
User entered 'l'	(D) (4), (b) (6)	20 Sep 2020 20:58:18

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:22:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered '22/Oct/2020 16:33'	System	22 Oct 2020 16:33:08

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:22:05

**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.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:34:07
User entered 'l'	(b) (4), (b) (6)	22 Oct 2020 16:33:08

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'USA-US103-2020-MRNA-1273-P301000001'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42



**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'Yes (Y)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered 'No (N)'	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42



US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:37:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:58:05
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:04:33
Amendment Manager: User entered empty.	System	14 Sep 2020 22:04:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Aug 2020 14:46:14
User entered (b) (6)	System	30 Aug 2020 14:45:42

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:44:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 01:01:52
User entered 'US' (non-conformant).	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:22:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 00:22:55
User entered '4'	System	22 Oct 2020 16:33:08
User entered '3'	System	20 Sep 2020 20:58:18
User entered '2'	System	13 Sep 2020 01:02:02
User entered '1'	System	30 Aug 2020 14:46:22

**US3592232**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:22:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered '11/Nov/2020 19:22'	System	12 Nov 2020 00:22:55

US3592232

Folder: SAE USA-US103-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:22:05

**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.	Terry Poling (b) (4)	28 Apr 2021 09:38:06
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 19:37:59
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 00:22:55