

US3292339 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:35:15

All time stamps listed in this document are displayed in GMT

US3292339

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:19:56

Generated On: 09 Jun 2021 16:35:15

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[Participant ID](#)

US3292339

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

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US3292339

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Date of Informed Consent ( <i>dd MMM yyyy</i> )	27 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 type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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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) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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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) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

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

US3292339

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

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

US3292339

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	IDIOPATHIC PULMONARY FIBROSIS
Start date (dd MMM yyyy)	UN JAN 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	HYPERTENSION
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 (6)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	VARICELLA
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 (8)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	GROIN HERNIA
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 (9)

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:40
Height (xxx.x)	175.0 cm
Weight (xxx.x)	68.8 kg
BMI (xxx.x)	22.46531 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) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:19:58

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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** RETIRED

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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) 23 Feb 2021 14:19:58

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188284

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) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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)	27 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:20
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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)	27 AUG 2020
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 13:42
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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.*

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 13:08 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 13:08

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) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	12:03 (24 HR)
Collection date and time (derived)	27 AUG 2020 12:03



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:48	27 AUG 2020 11:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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

97.6 °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

27 AUG 2020 13:45

PC Open Date & Time

27 AUG 2020 13:28

PC Close Date & Time

27 AUG 2020 15:58

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 27 AUG 2020 22:14

PC Open Date & Time 27 AUG 2020 16:53

PC Close Date & Time 28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**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

97.7 °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

29 AUG 2020 08:20

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

29 AUG 2020 19:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**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

98.6 °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

30 AUG 2020 20:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

01 SEP 2020 20:30

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

02 SEP 2020 22:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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

27 AUG 2020 13:46

PC Open Date & Time

27 AUG 2020 13:28

PC Close Date & Time

27 AUG 2020 15:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**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

27 AUG 2020 22:14

PC Open Date & Time

27 AUG 2020 16:53

PC Close Date & Time

28 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**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

29 AUG 2020 08:20

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**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

29 AUG 2020 19:58

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**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

30 AUG 2020 20:49

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**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

31 AUG 2020 18:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**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

01 SEP 2020 20:31

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**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

02 SEP 2020 22:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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 ☐

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 13:47
PC Open Date & Time	27 AUG 2020 13:28
PC Close Date & Time	27 AUG 2020 15:58

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**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 ☐

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 22:15
PC Open Date & Time	27 AUG 2020 16:53
PC Close Date & Time	28 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

50 of 2634

EAB) (1725)

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 08:21
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2634

EAB) (1725)

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:58
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 2634

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

56 of 2634

EAB) (1725)

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 18:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

58 of 2634

EAB) (1725)

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:32
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2634

EAB) (1725)

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:34
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292339

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

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*

US3292339

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292339

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

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)	1 OCT 2020
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 15:32
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)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

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)	1 OCT 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 16:52
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3292339

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 16:19 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 16:19

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

US3292339

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	15:42 (24 HR)
Collection date and time (derived)	1 OCT 2020 15:42

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:55	1 OCT 2020 15:55
Nasopharyngeal Swab 2	No		

US3292339

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 16:54

PC Open Date & Time

01 OCT 2020 16:39

PC Close Date & Time

01 OCT 2020 19:09

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	02 OCT 2020 06:55
PC Open Date & Time	01 OCT 2020 20:04
PC Close Date & Time	02 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 20:12

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**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

03 OCT 2020 20:35

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**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

97.3 °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

04 OCT 2020 20:46

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:02

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

06 OCT 2020 19:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**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.

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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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 21:44

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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

01 OCT 2020 16:55

PC Open Date & Time

01 OCT 2020 16:39

PC Close Date & Time

01 OCT 2020 19:09

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**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

02 OCT 2020 06:56

PC Open Date & Time

01 OCT 2020 20:04

PC Close Date & Time

02 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**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

02 OCT 2020 20:12

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**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

03 OCT 2020 20:35

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**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

04 OCT 2020 20:46

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 19:02

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 19:13

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**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

07 OCT 2020 21:44

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**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 ☐

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 16:56
PC Open Date & Time	01 OCT 2020 16:39
PC Close Date & Time	01 OCT 2020 19:09

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**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 ☐

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 06:56
PC Open Date & Time	01 OCT 2020 20:04
PC Close Date & Time	02 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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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EAB) (1725)

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 20:13
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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  
EAB) (1725)

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US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:36
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:46
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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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EAB) (1725)

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:03
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

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EAB) (1725)

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 19:13
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

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EAB) (1725)

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 21:45
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59



US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 08 OCT 2020 19:31

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 08 OCT 2020 19:31

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

09 OCT 2020 22:20

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

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US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 19:31
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

<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 checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 22:20
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3292339

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292339

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 10:52
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 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)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292339

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

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.*

US3292339

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	11:01 (24 HR)
Collection date and time (derived)	27 OCT 2020 11:01

US3292339

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:59

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	27 OCT 2020 07:53:11
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

05 NOV 2020 12:04:15

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 00:06:00

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 NOV 2020 17:18:54
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 03:13:31
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

05 DEC 2020 13:41:52

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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	12 DEC 2020 00:02:32
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 21:51:00

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 05:13:41
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<b>TIMEPOINT</b>	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:39:57
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<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	09 JAN 2021 11:55:47
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<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	19 JAN 2021 11:34:12
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

27 JAN 2021 09:04:32

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<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	02 FEB 2021 15:07:30
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 19:38:37
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

13 FEB 2021 01:37:39

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59



US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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	22 FEB 2021 07:26:41
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 12:34:36
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 11:56:58
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 01:18:56

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 15:22:51

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 MAR 2021 08:31:47
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

06 APR 2021 15:02:42

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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

12 APR 2021 12:17:14

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59



US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<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	17 APR 2021 02:53:18
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 18:29:35

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 12:24:41
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

---

12 MAY 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	29 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JUN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	19 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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 <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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JAN 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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°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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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13 APR 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	02 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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 ☐



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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27 JUL 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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30 JUL 2022 00:01

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03 AUG 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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07 SEP 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 SEP 2022 00:01

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14 SEP 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

**US3292339**

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

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**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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17 SEP 2022 00:01

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21 SEP 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292339**

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

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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[Patient Cloud Close Date & Time](#)

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19 OCT 2022 23:59

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US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**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 ☐

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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"/>

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3292339

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:35:15

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		01 MAR 2021 12:34:48



US3292339

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292339

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3292339

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

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.*

US3292339

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	10:11 (24 HR)
Collection date and time (derived)	25 MAR 2021 10:11

US3292339

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

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*

**US3292339**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:35:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292339

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:35:15

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"/>



**US3292339**

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

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

**Generated On: 09 Jun 2021 16:35:15**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3292339

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

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

Visit date (dd MMM yyyy)	21 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3292339

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Date of updated informed consent (dd MMM yyyy)	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3292339

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3292339

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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 JAN 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 09:55
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3292339

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	21 JAN 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 12:00
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292339

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

21 JAN 2021

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

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US3292339

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 11:29

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



US3292339

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	10:02 (24 HR)
Collection date and time (derived)	21 JAN 2021 10:02

US3292339

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	10:34
Collection Date and Time (derived)	21 JAN 2021 10:34

US3292339

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292339

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:19:58

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3292339

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

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)	26 FEB 2021
Time of assessment (00:00-23:59)	08:53 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 08:53
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

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)	26 FEB 2021
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:07
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3292339

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3292339

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 10:37 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:37

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292339

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3292339

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

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.*



US3292339

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:44:04

Generated On: 09 Jun 2021 16:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	10:11 (24 HR)
Collection date and time (derived)	25 MAR 2021 10:11

US3292339

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID	USA-US072-2020-MRNA-1273-P30 1000002
Adverse event	ANGIOEDEMA
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)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

Number of Days in ICU	1
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	

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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SUBJECT NOTIFIED SITE OF HOSPITALIZATION IN THE ICU DUE TO ALLERGIC REACTION TO LISINOPRIL. HE STATED THAT HE WAS TAKEN TO THE HOSPITAL AFTER MIDNIGHT, EARLY MORNING OF 17SEP2020, AFTER EXPERIENCING A 2 HOUR EPISODE OF PERSISTENT COUGHING. HE REPORTED THAT EMS WAS CALLED AFTER HE HAD NOTED SEVERE SWELLING OF HIS NECK AND DIFFICULTY BREATHING. AS PER SUBJECT, HE CANNOT RECALL WHAT MEDICATIONS HE WAS GIVEN WHILE INPATIENT, NOR THE PRESCRIPTION HE RECEIVED. HE STATES THAT HE WAS RELEASED MORNING OF 18SEP2020 WITH A DIAGNOSIS OF ANGIOEDEMA CAUSED BY AN ALLERGIC REACTION TO LISINOPRIL. MEDICAL RECORDS WILL BE REQUESTED ASAP AND UPDATES TO THIS REPORT WILL BE SUBMITTED. UPDATE 03NOV2020: DIAGNOSTIC TEST RESULTS. CHEST XRAY SHOWED NO ACUTE CARDIOPULMONARY FINDINGS. CT MAXILLOFACIAL WITH CONTRAST SHOWED: "EXTENSIVE LARYNGEAL

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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EDEMA WITH MARKEDLY  
THICKENED EPIGLOTTIS,  
PREVERTEBRAL SOFT TISSUE  
THICKENING, AND EXTENSIVE  
EDEMA AT THE BASE OF THE  
TONGUE AND IN THE  
SUBMANDIBULAR SPACE.  
APPEARANCE MOST  
SUGGESTIVE OF ANGIOEDEMA  
OR ALLERGIC REACTION. NO  
SOFT TISSUE GAS OR  
DRAINABLE ABSCESS TO  
SUGGEST INFECTION. THERE IS  
NARROWING OF THE AIRWAY  
BUT THE AIRWAY APPEARS  
PATENT AT THIS TIME."

---

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)	1

---

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID

Adverse event

URINARY TRACT INFECTION

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)

1 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 OCT 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 (2)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID	
Adverse event	INJECTION SITE PAIN
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)	12 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 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 checked="" 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 (3)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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 type="radio"/> Related <input checked="" 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: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID	
Adverse event	INJECTION SITE NUMBNESS
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)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 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 (4)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID

Adverse event

URINARY TRACT INFECTION

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)

1 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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 (6)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

AEID

Adverse event

FATIGUE (REACTOGENICITY)

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)

2 OCT 2020

Start time (00:00-23:59)

20:13 (24 HR)

AE start date and time (derived)

2 OCT 2020 20:13

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 OCT 2020

End time (00:00-23:59)

22:20 (24 HR)

AE End Date and Time (derived)

9 OCT 2020 22:20

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 18:35:24

Generated On: 09 Jun 2021 16:35:15

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 23 Feb 2021 14:19:57

**Generated On: 09 Jun 2021 16:35:15**

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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) 23 Apr 2021 18:35:25

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Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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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 UNK 2010	
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)	3	
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) 23 Apr 2021 18:35:25

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Name of Medication VITAMIN C

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 (3)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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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 UNK 2010	
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) 23 Apr 2021 18:35:25

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Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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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 UNK 2010	
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) 23 Apr 2021 18:35:25

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Name of Medication JANUMET

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 50/1000

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 (5)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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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 APR 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 (6)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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Name of Medication ACICLOVIR

Prophylaxis Yes ☐  
No ☒

Indication VARICELLA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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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 UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 SEP 2020	
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 (8)

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Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	1 OCT 2020	
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) 23 Apr 2021 18:35:25

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Name of Medication PIRFENIDONE

Prophylaxis Yes ☐  
No ☒

Indication IDIOPATHIC PULMONARY  
FIBROSIS

Dose per administration 801

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) 23 Apr 2021 18:35:25

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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 JAN 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)	3	
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 (10)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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Name of Medication BACTRIM(TRIMETHOPRIM /  
SULFAMETHOXAZOLE)

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 400/80

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 (10)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 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 (11)

Data signed: (b) (4) 23 Apr 2021 18:35:25

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Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 15

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 (11)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		01 OCT 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 (12)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 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 (13)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication DIPHENHYDRAMINE HCL

Prophylaxis Yes ☐  
No ☒

Indication ANGIOEDEMA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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 checked="" 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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication EPINEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication ANGIOEDEMA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication IOPAMIDOL

Prophylaxis Yes ☐  
No ☒

Indication CT CONTRAST

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 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 (16)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication ANGIOEDEMA

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 (16)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 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 (17)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication ANGIOEDEMA

Dose per administration 125

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) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 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 (18)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐  
No ☒

Indication ANGIOEDEMA

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

6 DAY TAPERING COURSE,  
(6,5,4,3,2,1)

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 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 (19)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication SULFAMETHOXAZOLE

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 800/160

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 (19)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 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 (20)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication 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 (20)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication SULFAMETHOXAZOLE /  
TRIMETHOPRIM

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 400/80

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 (21)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)	08 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 JAN 2021	
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"/>

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication AMOXICILLIN/CLAVULANATE

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT  
INFECTION/BLADDER  
PROSTATE HEALTH

Dose per administration 250/125

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)

407 of 2634

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
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"/>

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

Name of Medication TYLENOL CODEINE

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM CONCOMITANT  
PROCEDURE, GROIN HERNIA  
REPAIR

Dose per administration 30/300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

409 of 2634

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 18:35:25

Generated On: 09 Jun 2021 16:35:15

	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)		2 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 FEB 2021
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"/>

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Mar 2021 14:20:42

Generated On: 09 Jun 2021 16:35:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 SEP 2020	NECK/MAXILLOFACIAL CT	Adverse Event	
17 SEP 2020	CHEST X-RAY	Adverse Event	
2 FEB 2021	HERNIA REPAIR	Medical History	

US3292339

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:35:15

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

US3292339

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:35:15

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 ☐

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:14
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

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/OCT/2020 12:46
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

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/OCT/2020 19:49
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

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/NOV/2020 10:30
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



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 16:15
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

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 14:19:57

Generated On: 09 Jun 2021 16:35:15

SAEID	USA-US072-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/FEB/2021 10:02
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

Audit

US3292339 (Prod: Clinical Trials of Texas, Inc)

**US3292339**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:35:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:24:19
User entered 'US3292339'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:10

US3292339

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:27:58

US3292339

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:11

US3292339

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 18:27:58

US3292339

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'SCRN'	System	28 Aug 2020 18:27:58



US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:12

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '70'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'YEARS'	System	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '70'	System	27 Aug 2020 18:20:28

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'l'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18



**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:28:18

**US3292339**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:35:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:35:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:18

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28



US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Aug 2020'	System	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2020'	System	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Amendment 3 (3)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:28

US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:10:11



US3292339

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:35:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'l'	System	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:35:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:28:28

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:46
Data point term sent to Coder	System	28 Aug 2020 18:29:40
User entered 'Seasonal allergy'	(b) (4), (b) (6)	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un UNK 2015'	(b) (4), (b) (6)	28 Aug 2020 18:28:58

**US3292339**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered '0'		28 Aug 2020 18:28:58

**US3292339**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:28:58



**US3292339**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2015'	System	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2015'	System	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	28 Aug 2020 18:28:58

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Ureteric therapeutic procedures, PT: Urostomy, LLT: Ureterostomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:48:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:48:55
Data point term sent to Coder	System	28 Aug 2020 18:47:19
User entered 'Ureterostomy'	(b) (4), (b) (6)	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un UNK 2000'	(b) (4), (b) (6)	28 Aug 2020 18:47:10

**US3292339**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered '0'		28 Aug 2020 18:47:10



**US3292339**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:47:10

**US3292339**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered 'un UNK 2000'	(b) (4), (b) (6)	28 Aug 2020 18:47:10

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2000'	System	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2000'	System	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2000'	System	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2000'	System	28 Aug 2020 18:47:10

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Renal and urinary disorders, HLG: Ureteric disorders, HLT: Ureteric disorders NEC, PT: Ureteric stenosis, LLT: Ureteral stricture - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:40
Data point term sent to Coder	System	08 Sep 2020 17:19:23
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
User entered 'Ureteral stricture'	(b) (4), (b) (6)	29 Aug 2020 03:24:46



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered 'un UNK 2000'		29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:24:46

**US3292339**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered 'un UNK 2000'		29 Aug 2020 03:24:46

**US3292339**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2000'	System	29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2000'	System	29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2000'	System	29 Aug 2020 03:24:46



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2000'	System	29 Aug 2020 03:24:46

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Idiopathic pulmonary fibrosis, LLT: Idiopathic pulmonary fibrosis - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:03
Data point term sent to Coder	System	08 Sep 2020 17:19:23
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
User entered 'Idiopathic pulmonary fibrosis'	(b) (4), (b) (6)	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un Jan 2020'	(b) (4), (b) (6)	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:25:27

**US3292339**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:25:27

**US3292339**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2020'	System	29 Aug 2020 03:25:27



US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2020'	System	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:25:27

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:24:49
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)	08 Sep 2020 17:21:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 17:21:01
Data point term sent to Coder	System	08 Sep 2020 17:19:26
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
User entered 'hypertension'	(b) (4), (b) (6)	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un UNK 2018'	(b) (4), (b) (6)	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered '0'		29 Aug 2020 03:25:45

**US3292339**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:25:45

**US3292339**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:25:45



**US3292339**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2018'	System	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2018'	System	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:25:45

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:03
Data point term sent to Coder	System	08 Sep 2020 17:19:24
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
User entered 'type 2 diabetes'	(b) (4), (b) (6)	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un UNK 2016'	(b) (4), (b) (6)	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:26:07



US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:26:07

**US3292339**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2016'	System	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2016'	System	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:26:07

US3292339

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Varicella, LLT: Varicella - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:20:24
Data point term sent to Coder	System	08 Sep 2020 17:19:24
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
User entered 'varicella'	(b) (4), (b) (6)	29 Aug 2020 03:26:24



**US3292339**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered 'un UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 03:26:24

**US3292339**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:26:24

**US3292339**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered 'Yes (Y)'		29 Aug 2020 03:26:24

**US3292339**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:49
User entered empty.		29 Aug 2020 03:26:24

**US3292339**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:24:49
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:26:24

US3292339

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2000'	System	29 Aug 2020 03:26:24

US3292339

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2000'	System	29 Aug 2020 03:26:24

US3292339

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:26:24



US3292339

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	29 Aug 2020 03:26:24

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Groin hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Mar 2021 21:23:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 21:23:38
Data point term sent to Coder	System	19 Mar 2021 21:23:00
User entered 'Groin Hernia'	Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'un UNK 2019'	(b) (4) Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 2019'	System	19 Mar 2021 21:22:43



US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '2019'	System	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	19 Mar 2021 21:22:43

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:12:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:12:35
Data point term sent to Coder	System	25 Mar 2021 16:12:22
User entered 'Depression'	(b) (4), (b) (6)	25 Mar 2021 16:12:08

**US3292339**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'un UNK 1975'	(b) (4), (b) (6)	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:12:08

**US3292339**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 16:12:08

**US3292339**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 16:12:08



US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'Jan 1975'	System	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '1975'	System	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered empty.	System	25 Mar 2021 16:12:08

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:28:54

**US3292339**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '10:40'	(b) (4), (b) (6)	29 Aug 2020 03:28:54



US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '27 Aug 2020 10:40'	System	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '175.0' cm	(b) (4) (b) (4), (b) (6)	29 Aug 2020 03:28:54
DataPoint set to visible.	System	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '68.8' kg	(b) (4) (b) (4), (b) (6)	29 Aug 2020 03:28:54
DataPoint set to visible.	System	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered '22.46531'	System	29 Aug 2020 03:28:54
DataPoint set to visible.	System	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'kg/m2'	System	29 Aug 2020 03:28:54
DataPoint set to visible.	System	27 Aug 2020 18:20:32

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 07:09:22
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Dec 2020 16:59:03
User entered empty; reason for change Data Entry Error	(b) (4)	22 Dec 2020 16:58:50
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 17:29:49
User entered 'Other (Other)'	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kevin Martinez (b) (4)	31 Dec 2020 17:48:47
User entered missing code ND - Not Done.	(b) (4)	
	(b) (4), (b) (6)	29 Aug 2020 03:28:54



US3292339

Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per CDM: Response noted. Please update fields as Not Done. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 19:20:40
Query 'Per CDM: Response noted. Please update fields as Not Done. ' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	31 Dec 2020 17:49:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:48:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:06:39
User opened query 'Per CDM: Response noted. Please update fields as Not Done. ' (Site from DM).		30 Dec 2020 22:06:30
User closed query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' (Site from DM).		30 Dec 2020 22:06:30
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:11:16
Query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	30 Dec 2020 18:11:02
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 18:10:30
User entered empty; reason for change Data Entry Error	Kevin Martinez (b) (4)	30 Dec 2020 18:10:30
User opened query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 14:28:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'bpm'	System	31 Dec 2020 17:48:47
User entered empty.	System	30 Dec 2020 18:10:30
User entered 'bpm'	System	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 19:20:43
Query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	31 Dec 2020 17:49:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:48:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:07:26
User opened query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).	(b) (4)	30 Dec 2020 22:07:25
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:11:06
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Dec 2020 18:10:30
User entered empty; reason for change Data Entry Error	Kevin Martinez (b) (4)	30 Dec 2020 18:10:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'breaths/min'	System	31 Dec 2020 17:48:47
User entered empty.	System	30 Dec 2020 18:10:30
User entered 'breaths/min'	System	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).	(b) (4)	
Query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 19:20:45
Query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	31 Dec 2020 17:49:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Dec 2020 17:48:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:07:43
User opened query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).		30 Dec 2020 22:07:41
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:11:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	30 Dec 2020 18:10:30
User entered missing code ND - Not Done.	Kevin Martinez (b) (4)	30 Dec 2020 18:10:30
	(b) (4)	
	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'mmHg'	System	31 Dec 2020 17:48:47
User entered empty.	System	30 Dec 2020 18:10:30
User entered 'mmHg'	System	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 19:20:47
Query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	31 Dec 2020 17:49:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:48:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:07:57
User opened query ' <input type="checkbox"/> Per CDM: Response noted. Please update field as Not Done' (Site from DM).	(b) (4)	30 Dec 2020 22:07:55
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Kevin Martinez (b) (4)	30 Dec 2020 18:11:09
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Dec 2020 18:10:30
User entered empty; reason for change Data Entry Error	Kevin Martinez (b) (4)	30 Dec 2020 18:10:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:28:54

US3292339

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User entered 'mmHg'	System	31 Dec 2020 17:48:47
User entered empty.	System	30 Dec 2020 18:10:30
User entered 'mmHg'	System	29 Aug 2020 03:28:54



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30

US3292339

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:28:08

US3292339

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:28:08

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 03:29:32



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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'retired'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

**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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

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)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'l'	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:35:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 03:29:32



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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:30:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:29:32

US3292339

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:29:43

**US3292339**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:29:43

US3292339

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Aug 2020 03:29:43

US3292339

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'VISIT1'	System	29 Aug 2020 03:29:43

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:59:34

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '188284'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:59:34

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:59:34



US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

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)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:33:06

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

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)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:33:06

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:33:06

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:33:06

**US3292339**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:35:15**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:33:06

US3292339

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:35:15

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:07:00
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:25:01
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:24:58
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:12:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:16:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:16:37

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51



US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Pre-Dose (PREDOSE)'		29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '11:20'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '27 Aug 2020 11:20'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.2' C	(b) (4), (b) (6)	29 Aug 2020 03:32:51



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '78'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'bpm'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'breaths/min'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '129'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	29 Aug 2020 03:32:51



US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '76'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Post-Dose (POSTDOSE)'		29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

**US3292339**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '13:42'	(b) (4), (b) (6)	29 Aug 2020 03:32:51



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '27 Aug 2020 13:42'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.4' C	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '77'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'bpm'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'breaths/min'	System	29 Aug 2020 03:32:51



US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '139'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '77'	(b) (4), (b) (6)	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	29 Aug 2020 03:32:51

US3292339

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:32:56

US3292339

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:32:56

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 18:20:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '13:08'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered '27 Aug 2020 13:08'	System	27 Aug 2020 18:20:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'ONCE'	System	27 Aug 2020 18:20:48

US3292339

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 18:20:48



US3292339

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:33:47

US3292339

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:33:47

US3292339

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '12:03'	(b) (4), (b) (6)	29 Aug 2020 03:33:47

US3292339

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered '27 Aug 2020 12:03'	System	29 Aug 2020 03:33:47

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:34:05

**US3292339**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:35:15**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '11:48'	(b) (4), (b) (6)	29 Aug 2020 03:34:05



US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered '27 Aug 2020 11:48'	System	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 03:34:05

**US3292339**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:35:15**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered empty.	System	29 Aug 2020 03:34:05

US3292339

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 03:34:10

US3292339

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'I'	System	29 Aug 2020 03:34:10

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:45:29', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0269fada-3986-4a19-b277-79911498a207'	System	27 Aug 2020 18:45:54
User entered 'Yes (Y)'	System	27 Aug 2020 18:45:54

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:45:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0269fada-3986-4a19-b277-79911498a207' User entered '97.6'	System	27 Aug 2020 18:45:54
	System	27 Aug 2020 18:45:54

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:45:42', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0269fada-3986-4a19-b277-79911498a207'	System	27 Aug 2020 18:45:54
User entered 'No (N)'	System	27 Aug 2020 18:45:54

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:45:49', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0269fada-3986-4a19-b277-79911498a207' User entered '27 Aug 2020 13:45'	System	27 Aug 2020 18:45:54
	System	27 Aug 2020 18:45:54

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 13:28'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 15:58'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:17', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ffe83505-5aca-4659-9096-152a845e2f6e' User entered 'Yes (Y)'	System	28 Aug 2020 03:14:40
	System	28 Aug 2020 03:14:40



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ffe83505-5aca-4659-9096-152a845e2f6e' User entered '97.6'	System	28 Aug 2020 03:14:40
	System	28 Aug 2020 03:14:40

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:29', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ffe83505-5aca-4659-9096-152a845e2f6e'	System	28 Aug 2020 03:14:40
User entered 'No (N)'	System	28 Aug 2020 03:14:40

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ffe83505-5aca-4659-9096-152a845e2f6e'	System	28 Aug 2020 03:14:40
User entered '27 Aug 2020 22:14'	System	28 Aug 2020 03:14:40

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 16:53'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 2'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:19:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4c3891e0-5fcf-452a-abfc-58a002cc5a65'	System	29 Aug 2020 13:20:19
User entered 'Yes (Y)'	System	29 Aug 2020 13:20:19

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:19:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4c3891e0-5fcf-452a-abfc-58a002cc5a65' User entered '97.7'	System	29 Aug 2020 13:20:19
	System	29 Aug 2020 13:20:19



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4c3891e0-5fcf-452a-abfc-58a002cc5a65'	System	29 Aug 2020 13:20:19
User entered 'No (N)'	System	29 Aug 2020 13:20:19

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:17', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4c3891e0-5fcf-452a-abfc-58a002cc5a65' User entered '29 Aug 2020 08:20'	System	29 Aug 2020 13:20:19
	System	29 Aug 2020 13:20:19

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 3'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:56:13', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4aad8bb3-07ff-46f9-a878-21970339b441' User entered 'Yes (Y)'	System	30 Aug 2020 00:58:00
	System	30 Aug 2020 00:58:00

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:57:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4aad8bb3-07ff-46f9-a878-21970339b441' User entered '98.1'	System	30 Aug 2020 00:58:00
	System	30 Aug 2020 00:58:00

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:57:51', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4aad8bb3-07ff-46f9-a878-21970339b441'	System	30 Aug 2020 00:58:00
User entered 'No (N)'	System	30 Aug 2020 00:58:00



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:57:58', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4aad8bb3-07ff-46f9-a878-21970339b441' User entered '29 Aug 2020 19:57'	System	30 Aug 2020 00:58:00
	System	30 Aug 2020 00:58:00

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 4'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:47:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ad6942cc-a658-4d72-92fa-9697f6998051' User entered 'Yes (Y)'	System	31 Aug 2020 01:49:02
	System	31 Aug 2020 01:49:02

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:48:49', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ad6942cc-a658-4d72-92fa-9697f6998051' User entered '98.6'	System	31 Aug 2020 01:49:02
	System	31 Aug 2020 01:49:02

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:48:55', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ad6942cc-a658-4d72-92fa-9697f6998051'	System	31 Aug 2020 01:49:02
User entered 'No (N)'	System	31 Aug 2020 01:49:02

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:48:59', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ad6942cc-a658-4d72-92fa-9697f6998051' User entered '30 Aug 2020 20:48'	System	31 Aug 2020 01:49:02
	System	31 Aug 2020 01:49:02



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 5'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:33:11', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '40900e85-e264-499e-bc36-732c64f13789'	System	31 Aug 2020 23:39:12
User entered 'Yes (Y)'	System	31 Aug 2020 23:39:12

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:01', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '40900e85-e264-499e-bc36-732c64f13789' User entered '98.4'	System	31 Aug 2020 23:39:12
	System	31 Aug 2020 23:39:12

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '40900e85-e264-499e-bc36-732c64f13789'	System	31 Aug 2020 23:39:12
User entered 'No (N)'	System	31 Aug 2020 23:39:12

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '40900e85-e264-499e-bc36-732c64f13789' User entered '31 Aug 2020 18:39'	System	31 Aug 2020 23:39:12
	System	31 Aug 2020 23:39:12

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 6'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:23', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '74e2a23e-33e4-4703-bb42-338a22bf7922'	System	02 Sep 2020 01:30:45
User entered 'Yes (Y)'	System	02 Sep 2020 01:30:45

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '74e2a23e-33e4-4703-bb42-338a22bf7922' User entered '98.3'	System	02 Sep 2020 01:30:45
	System	02 Sep 2020 01:30:45

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '74e2a23e-33e4-4703-bb42-338a22bf7922'	System	02 Sep 2020 01:30:45
User entered 'No (N)'	System	02 Sep 2020 01:30:45

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '74e2a23e-33e4-4703-bb42-338a22bf7922'	System	02 Sep 2020 01:30:45
User entered '01 Sep 2020 20:30'	System	02 Sep 2020 01:30:45

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 7'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '14f4d918-f806-45f3-8a72-8adc79655812' User entered 'Yes (Y)'	System	03 Sep 2020 03:33:17
	System	03 Sep 2020 03:33:17

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '14f4d918-f806-45f3-8a72-8adc79655812' User entered '97.8'	System	03 Sep 2020 03:33:17
	System	03 Sep 2020 03:33:17

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '14f4d918-f806-45f3-8a72-8adc79655812' User entered 'No (N)'	System	03 Sep 2020 03:33:17
	System	03 Sep 2020 03:33:17

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:15', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '14f4d918-f806-45f3-8a72-8ade79655812' User entered '02 Sep 2020 22:33'	System	03 Sep 2020 03:33:17
	System	03 Sep 2020 03:33:17

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:45:59', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f150d5d5-bf29-43ef-8dd6-0774393801b1' User entered 'None (1)'	System	27 Aug 2020 18:46:24
	System	27 Aug 2020 18:46:24

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:08', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f150d5d5-bf29-43ef-8dd6-0774393801b1' User entered 'No (N)'	System	27 Aug 2020 18:46:24
	System	27 Aug 2020 18:46:24

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:13', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f150d5d5-bf29-43ef-8dd6-0774393801b1' User entered 'No (N)'	System	27 Aug 2020 18:46:24
	System	27 Aug 2020 18:46:24

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:16', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f150d5d5-bf29-43ef-8dd6-0774393801b1' User entered 'None (1)'	System	27 Aug 2020 18:46:24
	System	27 Aug 2020 18:46:24

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f150d5d5-bf29-43ef-8dd6-0774393801b1' User entered '27 Aug 2020 13:46'	System	27 Aug 2020 18:46:24
	System	27 Aug 2020 18:46:24

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 13:28'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 15:58'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '76af3f78-c1dc-4344-9dd3-a5287e33795f'	System	28 Aug 2020 03:14:58
User entered 'None (1)'	System	28 Aug 2020 03:14:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '76af3f78-c1dc-4344-9dd3-a5287e33795f' User entered 'No (N)'	System	28 Aug 2020 03:14:58
	System	28 Aug 2020 03:14:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '76af3f78-c1dc-4344-9dd3-a5287e33795f' User entered 'No (N)'	System	28 Aug 2020 03:14:58
	System	28 Aug 2020 03:14:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:51', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '76af3f78-c1dc-4344-9dd3-a5287e33795f' User entered 'None (1)'	System	28 Aug 2020 03:14:58
	System	28 Aug 2020 03:14:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:14:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '76af3f78-c1dc-4344-9dd3-a5287e33795f' User entered '27 Aug 2020 22:14'	System	28 Aug 2020 03:14:58
	System	28 Aug 2020 03:14:58

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 16:53'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 2'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:23', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b246577c-b986-48a0-bf15-1b12fa1ad170'	System	29 Aug 2020 13:20:37
User entered 'None (1)'	System	29 Aug 2020 13:20:37

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b246577c-b986-48a0-bf15-1b12fa1ad170' User entered 'No (N)'	System	29 Aug 2020 13:20:37
	System	29 Aug 2020 13:20:37

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:29', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b246577c-b986-48a0-bf15-1b12fa1ad170' User entered 'No (N)'	System	29 Aug 2020 13:20:37
	System	29 Aug 2020 13:20:37

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b246577c-b986-48a0-bf15-1b12fa1ad170' User entered 'None (1)'	System	29 Aug 2020 13:20:37
	System	29 Aug 2020 13:20:37

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b246577c-b986-48a0-bf15-1b12fa1ad170' User entered '29 Aug 2020 08:20'	System	29 Aug 2020 13:20:37
	System	29 Aug 2020 13:20:37

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 3'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7a53de76-23a0-4efb-99bc-486dbdbc187c' User entered 'None (1)'	System	30 Aug 2020 00:58:18
	System	30 Aug 2020 00:58:18

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7a53de76-23a0-4efb-99bc-486dbdbc187c' User entered 'No (N)'	System	30 Aug 2020 00:58:18
	System	30 Aug 2020 00:58:18

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:11', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7a53de76-23a0-4efb-99bc-486dbdbc187c' User entered 'No (N)'	System	30 Aug 2020 00:58:18
	System	30 Aug 2020 00:58:18

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:13', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7a53de76-23a0-4efb-99bc-486dbdbc187c' User entered 'None (1)'	System	30 Aug 2020 00:58:18
	System	30 Aug 2020 00:58:18

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:17', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7a53de76-23a0-4efb-99bc-486dbdbc187c' User entered '29 Aug 2020 19:58'	System	30 Aug 2020 00:58:18
	System	30 Aug 2020 00:58:18

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 4'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:03', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '659fb771-e0d0-4db6-bdd4-1e7aa35691a8' User entered 'None (1)'	System	31 Aug 2020 01:49:14
	System	31 Aug 2020 01:49:14

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '659fb771-e0d0-4db6-bdd4-1e7aa35691a8' User entered 'No (N)'	System	31 Aug 2020 01:49:14
	System	31 Aug 2020 01:49:14

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '659fb771-e0d0-4db6-bdd4-1e7aa35691a8' User entered 'No (N)'	System	31 Aug 2020 01:49:14
	System	31 Aug 2020 01:49:14

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '659fb771-e0d0-4db6-bdd4-1e7aa35691a8' User entered 'None (1)'	System	31 Aug 2020 01:49:14
	System	31 Aug 2020 01:49:14

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '659fb771-e0d0-4db6-bdd4-1e7aa35691a8' User entered '30 Aug 2020 20:49'	System	31 Aug 2020 01:49:14
	System	31 Aug 2020 01:49:14

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 5'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '23bb4026-50ad-4536-8e05-80df9cb14f47'	System	31 Aug 2020 23:39:34
User entered 'None (1)'	System	31 Aug 2020 23:39:34

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:14', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '23bb4026-50ad-4536-8e05-80df9cb14f47'	System	31 Aug 2020 23:39:34
User entered 'No (N)'	System	31 Aug 2020 23:39:34

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '23bb4026-50ad-4536-8e05-80df9cb14f47'	System	31 Aug 2020 23:39:34
User entered 'No (N)'	System	31 Aug 2020 23:39:34

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:27', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '23bb4026-50ad-4536-8e05-80df9cb14f47'	System	31 Aug 2020 23:39:34
User entered 'None (1)'	System	31 Aug 2020 23:39:34

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '23bb4026-50ad-4536-8e05-80df9cb14f47'	System	31 Aug 2020 23:39:34
User entered '31 Aug 2020 18:39'	System	31 Aug 2020 23:39:34

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 6'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc61c7f1-e152-4df8-bafd-b8096c69e2d8'	System	02 Sep 2020 01:31:04
User entered 'None (1)'	System	02 Sep 2020 01:31:04

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc61c7f1-e152-4df8-bafd-b8096c69e2d8' User entered 'No (N)'	System	02 Sep 2020 01:31:04
	System	02 Sep 2020 01:31:04

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc61c7f1-e152-4df8-bafd-b8096c69e2d8'	System	02 Sep 2020 01:31:04
User entered 'No (N)'	System	02 Sep 2020 01:31:04

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:30:57', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc61c7f1-e152-4df8-bafd-b8096c69e2d8'	System	02 Sep 2020 01:31:04
User entered 'None (1)'	System	02 Sep 2020 01:31:04

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:01', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc61c7f1-e152-4df8-bafd-b8096c69e2d8' User entered '01 Sep 2020 20:31'	System	02 Sep 2020 01:31:04
	System	02 Sep 2020 01:31:04

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 7'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f6cb858b-020f-4cfa-9f9a-43ff55edf22f'	System	03 Sep 2020 03:33:35
User entered 'None (1)'	System	03 Sep 2020 03:33:35

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f6cb858b-020f-4cfa-9f9a-43ff55edf22f' User entered 'No (N)'	System	03 Sep 2020 03:33:35
	System	03 Sep 2020 03:33:35

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f6cb858b-020f-4cfa-9f9a-43ff55edf22f' User entered 'No (N)'	System	03 Sep 2020 03:33:35
	System	03 Sep 2020 03:33:35

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:27', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f6cb858b-020f-4cfa-9f9a-43ff55edf22f' User entered 'None (1)'	System	03 Sep 2020 03:33:35
	System	03 Sep 2020 03:33:35

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f6cb858b-020f-4cfa-9f9a-43ff55edf22f' User entered '02 Sep 2020 22:33'	System	03 Sep 2020 03:33:35
	System	03 Sep 2020 03:33:35

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:31', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'None (0)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'None (0)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'None (0)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'None (0)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2' User entered 'None (0)'	System	27 Aug 2020 18:47:09
	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:46:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'None (0)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:47:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2'	System	27 Aug 2020 18:47:09
User entered 'No (N)'	System	27 Aug 2020 18:47:09

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T13:47:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe69755e-6bf5-4bee-8181-e706e4508ca2' User entered '27 Aug 2020 13:47'	System	27 Aug 2020 18:47:09
	System	27 Aug 2020 18:47:09



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 13:28'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 15:58'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:10', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:13', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:16', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered 'None (0)'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9'	System	28 Aug 2020 03:15:24
User entered 'No (N)'	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-27T22:15:23', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77ef26d2-fd81-43eb-a1d0-da9fd682a1b9' User entered '27 Aug 2020 22:15'	System	28 Aug 2020 03:15:24
	System	28 Aug 2020 03:15:24

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '27 Aug 2020 16:53'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 2'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:42', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:44', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:47', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:55', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:20:58', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'None (0)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:21:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered 'No (N)'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T08:21:08', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ca3a6ce3-8d15-4088-b834-ab93c83cb52e' User entered '29 Aug 2020 08:21'	System	29 Aug 2020 13:21:12
	System	29 Aug 2020 13:21:12

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 3'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:27', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'None (0)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered 'No (N)'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-29T19:58:42', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0326f161-1307-4459-a92f-d958e5fb519e' User entered '29 Aug 2020 19:58'	System	30 Aug 2020 00:58:45
	System	30 Aug 2020 00:58:45

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 4'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:16', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:18', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:38', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'None (0)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered 'No (N)'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-30T20:49:49', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dabadf70-9dd8-4469-a0ed-1ec6bb9d895a' User entered '30 Aug 2020 20:49'	System	31 Aug 2020 01:49:52
	System	31 Aug 2020 01:49:52

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 5'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'None (0)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:39:55', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered 'No (N)'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-08-31T18:40:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd631fc5-ac5a-42df-938e-bfd3090a265f' User entered '31 Aug 2020 18:40'	System	31 Aug 2020 23:40:02
	System	31 Aug 2020 23:40:02

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:20:48



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 6'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7' User entered 'None (0)'	System	02 Sep 2020 01:32:08
	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7'	System	02 Sep 2020 01:32:08
User entered 'Significant; prevents daily activity (3)'	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:33', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7' User entered 'None (0)'	System	02 Sep 2020 01:32:08
	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7' User entered 'None (0)'	System	02 Sep 2020 01:32:08
	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7'	System	02 Sep 2020 01:32:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:31:52', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7' User entered 'None (0)'	System	02 Sep 2020 01:32:08
	System	02 Sep 2020 01:32:08



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:32:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7' User entered 'No (N)'	System	02 Sep 2020 01:32:08
	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-01T20:32:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '72440c8c-3e3c-463a-b943-65317274fad7'	System	02 Sep 2020 01:32:08
User entered '01 Sep 2020 20:32'	System	02 Sep 2020 01:32:08

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 7'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:40', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05



US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'None (0)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:33:58', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered 'No (N)'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-09-02T22:34:01', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8e1a97b-fd28-4da6-a355-07c633478ded' User entered '02 Sep 2020 22:34'	System	03 Sep 2020 03:34:05
	System	03 Sep 2020 03:34:05

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:20:48

US3292339

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 21:18:45



US3292339

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '03 Sep 2020' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 15:52:55
User entered '3 Sep 2020'	Kristy Trevino (b) (4)	03 Sep 2020 21:18:45
	(b) (4)	

US3292339

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 21:18:45

US3292339

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 21:18:45

US3292339

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 21:19:13

US3292339

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	03 Sep 2020 21:19:13

US3292339

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	10 Sep 2020 18:58:51

US3292339

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '10 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	10 Sep 2020 18:58:51

US3292339

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	10 Sep 2020 18:58:51



US3292339

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	10 Sep 2020 18:58:51

US3292339

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	10 Sep 2020 18:58:58

US3292339

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	10 Sep 2020 18:58:58

US3292339

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	27 Jan 2021 18:42:55
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 18:42:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:42:31

US3292339

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 18:42:55
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:42:31

US3292339

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	27 Jan 2021 18:42:55
reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:42:31
User entered empty.		

US3292339

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:42:31

US3292339

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:28:57



US3292339

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	01 Oct 2020 21:28:57

US3292339

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:34:23

US3292339

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:34:23

US3292339

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 22:34:23

US3292339

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'VISIT2'	System	01 Oct 2020 22:34:23

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Pre-Dose (PREDOSE)'		01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:35:04



US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '15:32'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '1 Oct 2020 15:32'	System	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.7' C	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '101'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'bpm'	System	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 22:35:04



US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'breaths/min'	System	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '133'	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
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), (b) (6)	05 Nov 2020 19:17:01
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 with 'PER PI this is normal' (Site from System).	Dawn Killian (b) (4)	08 Oct 2020 19:07:43
User opened query 'Diastolic Blood Pressure reported System 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).		01 Oct 2020 22:35:04
User entered '59'	(b) (4), (b) (6)	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	01 Oct 2020 22:35:04

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Post-Dose (POSTDOSE)'		01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:36:09



US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16:52'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '1 Oct 2020 16:52'	System	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.4' C	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '97'	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'bpm'	System	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 22:36:09



US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'breaths/min'	System	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '146'	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '73'	(b) (4), (b) (6)	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	01 Oct 2020 22:36:09

US3292339

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:18

US3292339

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:36:18

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15



US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16:19'	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '1 Oct 2020 16:19'	System	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'ONCE'	System	01 Oct 2020 21:29:15



US3292339

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 21:29:15

US3292339

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:31

US3292339

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:36:31

US3292339

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '15:42'	(b) (4), (b) (6)	01 Oct 2020 22:36:31

US3292339

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '1 Oct 2020 15:42'	System	01 Oct 2020 22:36:31

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4) System	05 Oct 2020 15:52:10
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	05 Oct 2020 15:52:10
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:52:10
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	01 Oct 2020 22:36:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:41



US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '15:55'	(b) (4), (b) (6)	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '1 Oct 2020 15:55'	System	05 Oct 2020 15:52:10
User entered empty.	System	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered empty.	System	01 Oct 2020 22:36:41

US3292339

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:47

US3292339

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'l'	System	01 Oct 2020 22:36:47



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '64a5a940-b493-4c78-a52a-af5cea46a53c' User entered 'Yes (Y)'	System	01 Oct 2020 21:54:42
	System	01 Oct 2020 21:54:42

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:28', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '64a5a940-b493-4c78-a52a-af5cea46a53c' User entered '97.5'	System	01 Oct 2020 21:54:42
	System	01 Oct 2020 21:54:42

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:34', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '64a5a940-b493-4c78-a52a-af5cea46a53c'	System	01 Oct 2020 21:54:42
User entered 'No (N)'	System	01 Oct 2020 21:54:42

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:38', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '64a5a940-b493-4c78-a52a-af5cea46a53c' User entered '01 Oct 2020 16:54'	System	01 Oct 2020 21:54:42
	System	01 Oct 2020 21:54:42

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 19:09'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:55:34', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cc7666c0-e63c-4484-824d-c481c322b070' User entered 'Yes (Y)'	System	02 Oct 2020 11:55:52
	System	02 Oct 2020 11:55:52

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:55:40', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cc7666c0-e63c-4484-824d-c481c322b070' User entered '97.1'	System	02 Oct 2020 11:55:52
	System	02 Oct 2020 11:55:52

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:55:44', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cc7666c0-e63c-4484-824d-c481c322b070'	System	02 Oct 2020 11:55:52
User entered 'No (N)'	System	02 Oct 2020 11:55:52

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:55:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cc7666c0-e63c-4484-824d-c481c322b070' User entered '02 Oct 2020 06:55'	System	02 Oct 2020 11:55:52
	System	02 Oct 2020 11:55:52

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 20:04'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 2'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df9c8191-3aa2-4749-b522-e0e95990657e' User entered 'Yes (Y)'	System	03 Oct 2020 01:12:39
	System	03 Oct 2020 01:12:39



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:28', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df9c8191-3aa2-4749-b522-e0e95990657e' User entered '97.4'	System	03 Oct 2020 01:12:39
	System	03 Oct 2020 01:12:39

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df9c8191-3aa2-4749-b522-e0e95990657e'	System	03 Oct 2020 01:12:39
User entered 'No (N)'	System	03 Oct 2020 01:12:39

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df9c8191-3aa2-4749-b522-e0e95990657e' User entered '02 Oct 2020 20:12'	System	03 Oct 2020 01:12:39
	System	03 Oct 2020 01:12:39

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 3'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:34:45', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1d15402-6bd1-4ce9-9aa1-7cdcb899d2c1' User entered 'Yes (Y)'	System	04 Oct 2020 01:35:05
	System	04 Oct 2020 01:35:05

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:34:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1d15402-6bd1-4ce9-9aa1-7cdcb899d2c1' User entered '97.3'	System	04 Oct 2020 01:35:05
	System	04 Oct 2020 01:35:05



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:34:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1d15402-6bd1-4ce9-9aa1-7cdcb899d2c1' User entered 'No (N)'	System	04 Oct 2020 01:35:05
	System	04 Oct 2020 01:35:05

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1d15402-6bd1-4ce9-9aa1-7cdcb899d2c1' User entered '03 Oct 2020 20:35'	System	04 Oct 2020 01:35:05
	System	04 Oct 2020 01:35:05

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 4'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:01', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fcfd2713-b2a9-435c-a164-4a70ea582fad' User entered 'Yes (Y)'	System	05 Oct 2020 01:46:16
	System	05 Oct 2020 01:46:16

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:06', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fcfd2713-b2a9-435c-a164-4a70ea582fad' User entered '97.3'	System	05 Oct 2020 01:46:16
	System	05 Oct 2020 01:46:16

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fcfd2713-b2a9-435c-a164-4a70ea582fad'	System	05 Oct 2020 01:46:16
User entered 'No (N)'	System	05 Oct 2020 01:46:16



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:15', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fcfd2713-b2a9-435c-a164-4a70ea582fad' User entered '04 Oct 2020 20:46'	System	05 Oct 2020 01:46:16
	System	05 Oct 2020 01:46:16

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 5'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:27', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b14b3cd6-99ad-49bc-8f81-8879c7587497' User entered 'Yes (Y)'	System	06 Oct 2020 00:02:47
	System	06 Oct 2020 00:02:47

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:38', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b14b3cd6-99ad-49bc-8f81-8879c7587497' User entered '97.4'	System	06 Oct 2020 00:02:47
	System	06 Oct 2020 00:02:47

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b14b3cd6-99ad-49bc-8f81-8879c7587497'	System	06 Oct 2020 00:02:47
User entered 'No (N)'	System	06 Oct 2020 00:02:47

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:44', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b14b3cd6-99ad-49bc-8f81-8879c7587497' User entered '05 Oct 2020 19:02'	System	06 Oct 2020 00:02:47
	System	06 Oct 2020 00:02:47



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 6'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:12:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8a91a830-14ad-4b72-bea9-fcc54cd24397'	System	07 Oct 2020 00:13:26
User entered 'Yes (Y)'	System	07 Oct 2020 00:13:26

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:12:49', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8a91a830-14ad-4b72-bea9-fcc54cd24397' User entered '98.3'	System	07 Oct 2020 00:13:26
	System	07 Oct 2020 00:13:26

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:12:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8a91a830-14ad-4b72-bea9-fcc54cd24397'	System	07 Oct 2020 00:13:26
User entered 'No (N)'	System	07 Oct 2020 00:13:26

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:12:59', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8a91a830-14ad-4b72-bea9-fcc54cd24397' User entered '06 Oct 2020 19:12'	System	07 Oct 2020 00:13:26
	System	07 Oct 2020 00:13:26

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 7'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:14', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '02d81e46-c725-4889-a7af-6d47ae8383f0' User entered 'Yes (Y)'	System	08 Oct 2020 02:44:29
	System	08 Oct 2020 02:44:29

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:21', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '02d81e46-c725-4889-a7af-6d47ae8383f0' User entered '97.5'	System	08 Oct 2020 02:44:29
	System	08 Oct 2020 02:44:29

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '02d81e46-c725-4889-a7af-6d47ae8383f0'	System	08 Oct 2020 02:44:29
User entered 'No (N)'	System	08 Oct 2020 02:44:29

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:27', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '02d81e46-c725-4889-a7af-6d47ae8383f0' User entered '07 Oct 2020 21:44'	System	08 Oct 2020 02:44:29
	System	08 Oct 2020 02:44:29

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:45', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df47a3af-d342-45ac-9172-46cf6c165e4f'	System	01 Oct 2020 21:55:10
User entered 'None (1)'	System	01 Oct 2020 21:55:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:51', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df47a3af-d342-45ac-9172-46cf6c165e4f' User entered 'No (N)'	System	01 Oct 2020 21:55:10
	System	01 Oct 2020 21:55:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:54:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df47a3af-d342-45ac-9172-46cf6c165e4f' User entered 'No (N)'	System	01 Oct 2020 21:55:10
	System	01 Oct 2020 21:55:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df47a3af-d342-45ac-9172-46cf6c165e4f'	System	01 Oct 2020 21:55:10
User entered 'None (1)'	System	01 Oct 2020 21:55:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'df47a3af-d342-45ac-9172-46cf6c165e4f' User entered '01 Oct 2020 16:55'	System	01 Oct 2020 21:55:10
	System	01 Oct 2020 21:55:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 19:09'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:55:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b9999d6f-50d1-4db3-b429-62f62b39accb'	System	02 Oct 2020 11:56:10
User entered 'None (1)'	System	02 Oct 2020 11:56:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b9999d6f-50d1-4db3-b429-62f62b39accb' User entered 'No (N)'	System	02 Oct 2020 11:56:10
	System	02 Oct 2020 11:56:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b9999d6f-50d1-4db3-b429-62f62b39accb' User entered 'No (N)'	System	02 Oct 2020 11:56:10
	System	02 Oct 2020 11:56:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b9999d6f-50d1-4db3-b429-62f62b39accb'	System	02 Oct 2020 11:56:10
User entered 'None (1)'	System	02 Oct 2020 11:56:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b9999d6f-50d1-4db3-b429-62f62b39accb' User entered '02 Oct 2020 06:56'	System	02 Oct 2020 11:56:10
	System	02 Oct 2020 11:56:10

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 20:04'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 2'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cae0b204-c0d0-473b-849f-ff1500e44bcd'	System	03 Oct 2020 01:12:55
User entered 'None (1)'	System	03 Oct 2020 01:12:55

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:44', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cae0b204-c0d0-473b-849f-ff1500e44bcd' User entered 'No (N)'	System	03 Oct 2020 01:12:55
	System	03 Oct 2020 01:12:55

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:47', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cae0b204-c0d0-473b-849f-ff1500e44bcd' User entered 'No (N)'	System	03 Oct 2020 01:12:55
	System	03 Oct 2020 01:12:55

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cae0b204-c0d0-473b-849f-ff1500e44bcd'	System	03 Oct 2020 01:12:55
User entered 'None (1)'	System	03 Oct 2020 01:12:55

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:12:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'cae0b204-c0d0-473b-849f-ff1500e44bcd' User entered '02 Oct 2020 20:12'	System	03 Oct 2020 01:12:55
	System	03 Oct 2020 01:12:55

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 3'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '83963e22-d1da-4b1d-ba83-178a48fdbec'	System	04 Oct 2020 01:35:35
User entered 'None (1)'	System	04 Oct 2020 01:35:35

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '83963e22-d1da-4b1d-ba83-178a48fdfeb'	System	04 Oct 2020 01:35:35
User entered 'No (N)'	System	04 Oct 2020 01:35:35

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:21', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '83963e22-d1da-4b1d-ba83-178a48fdfeb'	System	04 Oct 2020 01:35:35
User entered 'No (N)'	System	04 Oct 2020 01:35:35

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '83963e22-d1da-4b1d-ba83-178a48fdfeb'	System	04 Oct 2020 01:35:35
User entered 'None (1)'	System	04 Oct 2020 01:35:35

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:33', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '83963e22-d1da-4b1d-ba83-178a48fdfeb' User entered '03 Oct 2020 20:35'	System	04 Oct 2020 01:35:35
	System	04 Oct 2020 01:35:35

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 4'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:19', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0a5500f2-0a93-4c8c-9c4f-f48c8de416cc'	System	05 Oct 2020 01:46:30
User entered 'None (1)'	System	05 Oct 2020 01:46:30

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0a5500f2-0a93-4c8c-9c4f-f48c8de416cc' User entered 'No (N)'	System	05 Oct 2020 01:46:30
	System	05 Oct 2020 01:46:30

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0a5500f2-0a93-4c8c-9c4f-f48c8de416cc' User entered 'No (N)'	System	05 Oct 2020 01:46:30
	System	05 Oct 2020 01:46:30

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0a5500f2-0a93-4c8c-9c4f-f48c8de416cc'	System	05 Oct 2020 01:46:30
User entered 'None (1)'	System	05 Oct 2020 01:46:30

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:28', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0a5500f2-0a93-4c8c-9c4f-f48c8de416cc' User entered '04 Oct 2020 20:46'	System	05 Oct 2020 01:46:30
	System	05 Oct 2020 01:46:30

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 5'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dc96d2f2-9d8b-4441-8f69-e45fac723cce'	System	06 Oct 2020 00:03:01
User entered 'None (1)'	System	06 Oct 2020 00:03:01

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:52', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dc96d2f2-9d8b-4441-8f69-e45fac723cce' User entered 'No (N)'	System	06 Oct 2020 00:03:01
	System	06 Oct 2020 00:03:01

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dc96d2f2-9d8b-4441-8f69-e45fac723cce' User entered 'No (N)'	System	06 Oct 2020 00:03:01
	System	06 Oct 2020 00:03:01

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dc96d2f2-9d8b-4441-8f69-e45fac723cce'	System	06 Oct 2020 00:03:01
User entered 'None (1)'	System	06 Oct 2020 00:03:01

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:02:59', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'dc96d2f2-9d8b-4441-8f69-e45fac723cce' User entered '05 Oct 2020 19:02'	System	06 Oct 2020 00:03:01
	System	06 Oct 2020 00:03:01

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 6'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:03', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '84c17f60-838c-43e2-8669-30bddc013731'	System	07 Oct 2020 00:13:33
User entered 'None (1)'	System	07 Oct 2020 00:13:33

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:05', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '84c17f60-838c-43e2-8669-30bddc013731'	System	07 Oct 2020 00:13:33
User entered 'No (N)'	System	07 Oct 2020 00:13:33

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '84c17f60-838c-43e2-8669-30bddc013731' User entered 'No (N)'	System	07 Oct 2020 00:13:33
	System	07 Oct 2020 00:13:33

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:10', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '84c17f60-838c-43e2-8669-30bddc013731'	System	07 Oct 2020 00:13:33
User entered 'None (1)'	System	07 Oct 2020 00:13:33

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '84c17f60-838c-43e2-8669-30bddc013731' User entered '06 Oct 2020 19:13'	System	07 Oct 2020 00:13:33
	System	07 Oct 2020 00:13:33

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 7'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b45940c4-99f5-45f0-9b88-5787a45e28f5'	System	08 Oct 2020 02:44:42
User entered 'None (1)'	System	08 Oct 2020 02:44:42

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:33', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b45940c4-99f5-45f0-9b88-5787a45e28f5' User entered 'No (N)'	System	08 Oct 2020 02:44:42
	System	08 Oct 2020 02:44:42

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b45940c4-99f5-45f0-9b88-5787a45e28f5' User entered 'No (N)'	System	08 Oct 2020 02:44:42
	System	08 Oct 2020 02:44:42

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b45940c4-99f5-45f0-9b88-5787a45e28f5'	System	08 Oct 2020 02:44:42
User entered 'None (1)'	System	08 Oct 2020 02:44:42

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:40', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'b45940c4-99f5-45f0-9b88-5787a45e28f5' User entered '07 Oct 2020 21:44'	System	08 Oct 2020 02:44:42
	System	08 Oct 2020 02:44:42

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:16', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:31', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:55:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'None (0)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:56:03', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered 'No (N)'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-01T16:56:09', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '03263e18-8398-413d-8a43-899a026ab8ca' User entered '01 Oct 2020 16:56'	System	01 Oct 2020 21:56:11
	System	01 Oct 2020 21:56:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 19:09'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:19', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:45', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'None (0)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered 'No (N)'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T06:56:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'ec027eff-8410-4a09-adab-c7568dceb13c' User entered '02 Oct 2020 06:56'	System	02 Oct 2020 11:56:58
	System	02 Oct 2020 11:56:58

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '01 Oct 2020 20:04'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 2'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered 'None (0)'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403'	System	03 Oct 2020 01:13:39
User entered 'Some interference with activity (2)'	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:14', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered 'None (0)'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:18', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403'	System	03 Oct 2020 01:13:39
User entered 'Some interference with activity (2)'	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered 'None (0)'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:29', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered 'None (0)'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:34', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered 'No (N)'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-02T20:13:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5ad083ac-9bda-4f90-b34e-86337436b403' User entered '02 Oct 2020 20:13'	System	03 Oct 2020 01:13:39
	System	03 Oct 2020 01:13:39

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 3'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered 'None (0)'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0'	System	04 Oct 2020 01:36:11
User entered 'No interference with activity (1)'	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered 'None (0)'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0'	System	04 Oct 2020 01:36:11
User entered 'No interference with activity (1)'	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:35:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered 'None (0)'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:36:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered 'None (0)'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:36:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered 'No (N)'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-03T20:36:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '108ee062-c49a-4b46-8581-f0c0203af7a0' User entered '03 Oct 2020 20:36'	System	04 Oct 2020 01:36:11
	System	04 Oct 2020 01:36:11

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 4'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:44', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'None (0)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:47', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered 'No (N)'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-04T20:46:50', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '656e8049-4328-41c2-94d5-c5c89bf184c2' User entered '04 Oct 2020 20:46'	System	05 Oct 2020 01:46:52
	System	05 Oct 2020 01:46:52

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 5'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:04', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:08', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:10', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:13', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:15', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:17', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'None (0)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered 'No (N)'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-05T19:03:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9cb644a7-9bf7-4e28-a048-cd4c6c6d1701' User entered '05 Oct 2020 19:03'	System	06 Oct 2020 00:03:27
	System	06 Oct 2020 00:03:27



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 6'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:16', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:18', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:22', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'None (0)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8'	System	07 Oct 2020 00:13:37
User entered 'No (N)'	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-06T19:13:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '97b329b0-86fe-47cb-890f-0ffb6dd9b9e8' User entered '06 Oct 2020 19:13'	System	07 Oct 2020 00:13:37
	System	07 Oct 2020 00:13:37

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	01 Oct 2020 21:29:15
User entered 'Day 7'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7'	System	08 Oct 2020 02:45:19
User entered 'No interference with activity (1)'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:52', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7'	System	08 Oct 2020 02:45:19
User entered 'No interference with activity (1)'	System	08 Oct 2020 02:45:19



US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:44:57', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7' User entered 'None (0)'	System	08 Oct 2020 02:45:19
	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:45:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7' User entered 'None (0)'	System	08 Oct 2020 02:45:19
	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:45:02', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7' User entered 'None (0)'	System	08 Oct 2020 02:45:19
	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:45:07', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7' User entered 'None (0)'	System	08 Oct 2020 02:45:19
	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:45:11', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7'	System	08 Oct 2020 02:45:19
User entered 'No (N)'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-07T21:45:14', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fe3b85df-233e-4df3-8e86-db75106e5cb7' User entered '07 Oct 2020 21:45'	System	08 Oct 2020 02:45:19
	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:29:15

US3292339

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:29:15



US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	08 Oct 2020 02:45:19
User entered 'Day 8'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:14', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'bb7d852b-b148-4025-b26c-0c45b6a3020f' User entered 'None (0)'	System	09 Oct 2020 00:31:25
	System	09 Oct 2020 00:31:25

US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:21', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'bb7d852b-b148-4025-b26c-0c45b6a3020f' User entered '08 Oct 2020 19:31'	System	09 Oct 2020 00:31:25
	System	09 Oct 2020 00:31:25

US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	08 Oct 2020 02:45:19
User entered 'Day 8'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1eecfe2-30d5-481e-8188-e7bca5e403f0'	System	09 Oct 2020 00:31:38
User entered 'No interference with activity (1)'	System	09 Oct 2020 00:31:38

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:35', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'a1eecfe2-30d5-481e-8188-e7bca5e403f0' User entered '08 Oct 2020 19:31'	System	09 Oct 2020 00:31:38
	System	09 Oct 2020 00:31:38



US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	08 Oct 2020 02:45:19
User entered 'Day 9'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-09T22:20:29', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '91004244-fe84-4f9c-a6bd-4d318bc83098' User entered 'None (0)'	System	10 Oct 2020 03:20:36
	System	10 Oct 2020 03:20:36

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-09T22:20:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '91004244-fe84-4f9c-a6bd-4d318bc83098' User entered '09 Oct 2020 22:20'	System	10 Oct 2020 03:20:36
	System	10 Oct 2020 03:20:36

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	08 Oct 2020 02:45:19
User entered 'Day 8'	System	08 Oct 2020 02:45:19



US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0393f1db-f922-4839-a526-f95e040ca361' User entered 'No (N)'	System	09 Oct 2020 00:31:48
	System	09 Oct 2020 00:31:48

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-08T19:31:45', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0393f1db-f922-4839-a526-f95e040ca361' User entered '08 Oct 2020 19:31'	System	09 Oct 2020 00:31:48
	System	09 Oct 2020 00:31:48

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
DataPoint Activated.	System	09 Oct 2020 00:31:38
DataPoint Inactivated.	System	09 Oct 2020 00:31:25
Data entry locked.	System	08 Oct 2020 02:45:19
User entered 'Day 9'	System	08 Oct 2020 02:45:19

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-09T22:20:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4a9f6ad5-6474-4b2a-bfea-ca21bda9135c'	System	10 Oct 2020 03:20:43
User entered 'No (N)'	System	10 Oct 2020 03:20:43
DataPoint Activated.	System	09 Oct 2020 00:31:38
DataPoint Inactivated.	System	09 Oct 2020 00:31:25

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-09T22:20:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '4a9f6ad5-6474-4b2a-bfea-ca21bda9135c'	System	10 Oct 2020 03:20:43
User entered '09 Oct 2020 22:20'	System	10 Oct 2020 03:20:43
DataPoint Activated.	System	09 Oct 2020 00:31:38
DataPoint Inactivated.	System	09 Oct 2020 00:31:25

US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
DataPoint Activated.	System	09 Oct 2020 00:31:38
DataPoint Inactivated.	System	09 Oct 2020 00:31:25
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:45:19



US3292339

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
DataPoint Activated.	System	09 Oct 2020 00:31:38
DataPoint Inactivated.	System	09 Oct 2020 00:31:25
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:45:19

US3292339

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	08 Oct 2020 18:26:55

US3292339

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '8 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	08 Oct 2020 18:26:55

US3292339

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	08 Oct 2020 18:26:55

US3292339

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	08 Oct 2020 18:26:55

US3292339

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	08 Oct 2020 18:27:03

US3292339

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	08 Oct 2020 18:27:03

US3292339

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	15 Oct 2020 20:32:02



US3292339

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '15 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	15 Oct 2020 20:32:02

US3292339

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	15 Oct 2020 20:32:02

US3292339

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:32:02

US3292339

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	15 Oct 2020 20:32:10

US3292339

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	15 Oct 2020 20:32:10

US3292339

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	22 Oct 2020 16:06:04

US3292339

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '22 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	22 Oct 2020 16:06:04

US3292339

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	22 Oct 2020 16:06:04



US3292339

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	22 Oct 2020 16:06:04

US3292339

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	22 Oct 2020 16:06:11

US3292339

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	22 Oct 2020 16:06:11

US3292339

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:04:27

US3292339

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:04:27

**US3292339**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 18:04:27

US3292339

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'VISIT3'	System	27 Oct 2020 18:04:27

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:05:08



US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

**US3292339**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '10:52'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '27 Oct 2020 10:52'	System	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.5' C	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

**US3292339**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '84'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'bpm'	System	27 Oct 2020 18:05:08



US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '16'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'breaths/min'	System	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '116'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '86'	(b) (4), (b) (6)	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'mmHg'	System	27 Oct 2020 18:05:08

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25

US3292339

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25



US3292339

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 18:05:12

**US3292339**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:35:15**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:05:12

US3292339

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:05:24

US3292339

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:05:24

US3292339

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '11:01'	(b) (4), (b) (6)	27 Oct 2020 18:05:24

US3292339

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered '27 Oct 2020 11:01'	System	27 Oct 2020 18:05:24

US3292339

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:05:28

US3292339

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:52:25
User entered 'I'	System	27 Oct 2020 18:05:28



US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 64'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:50:42', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c'	System	27 Oct 2020 12:53:22
User entered 'Yes (Y)'	System	27 Oct 2020 12:53:22

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:50:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c'	System	27 Oct 2020 12:53:22
User entered 'No (N)'	System	27 Oct 2020 12:53:22

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:52:28', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c'	System	27 Oct 2020 12:53:22
User entered 'No (N)'	System	27 Oct 2020 12:53:22

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:52:31', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c'	System	27 Oct 2020 12:53:22
User entered 'Yes (Y)'	System	27 Oct 2020 12:53:22

US3292339

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:52:47', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c'	System	27 Oct 2020 12:53:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 12:53:22

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-10-27T07:53:11', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fc852f53-1c25-4ac6-bd4d-5a0c7a3d2e3c' User entered '27 Oct 2020 07:53:11'	System	27 Oct 2020 12:53:22
	System	27 Oct 2020 12:53:22

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 18:20:48



US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 71'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-05T12:04:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3c3d25e0-a28b-4115-9170-48aa2c697ade' User entered 'No (N)'	System	05 Nov 2020 18:04:19
	System	05 Nov 2020 18:04:19

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-05T12:03:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3c3d25e0-a28b-4115-9170-48aa2c697ade'	System	05 Nov 2020 18:04:19
User entered 'No (N)'	System	05 Nov 2020 18:04:19

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-05T12:04:15', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3c3d25e0-a28b-4115-9170-48aa2c697ade' User entered '05 Nov 2020 12:04:15'	System	05 Nov 2020 18:04:19
	System	05 Nov 2020 18:04:19

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered 'Day 78'	System	27 Aug 2020 18:20:48



US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-10T00:05:52', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8910924-24e0-478b-8f2b-cd47d66647a7'	System	10 Nov 2020 06:06:05
User entered 'No (N)'	System	10 Nov 2020 06:06:05

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-10T00:05:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8910924-24e0-478b-8f2b-cd47d66647a7'	System	10 Nov 2020 06:06:05
User entered 'No (N)'	System	10 Nov 2020 06:06:05

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-10T00:06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'e8910924-24e0-478b-8f2b-ed47d66647a7' User entered '10 Nov 2020 00:06:00'	System	10 Nov 2020 06:06:05
	System	10 Nov 2020 06:06:05

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 18:20:48

US3292339

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:19:08
Data entry locked.	System	27 Aug 2020 18:20:48
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 18:20:48

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-24T17:18:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '1a2df221-72e0-4b8d-8a5c-0ddb7238ddd' User entered 'No (N)'	System	24 Nov 2020 23:18:56
	System	24 Nov 2020 23:18:56

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-24T17:18:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '1a2df221-72e0-4b8d-8a5c-0ddb7238ddd' User entered 'No (N)'	System	24 Nov 2020 23:18:56



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-24T17:18:54', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '1a2df221-72e0-4b8d-8a5c-0ddb7238ddd' User entered '24 Nov 2020 17:18:54'	System	24 Nov 2020 23:18:56
	System	24 Nov 2020 23:18:56

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-28T03:13:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '65b0093a-1ad2-4cbc-8736-9bc422d1565a' User entered 'No (N)'	System	28 Nov 2020 09:13:36

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-28T03:13:25', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '65b0093a-1ad2-4cbc-8736-9bc422d1565a' User entered 'No (N)'	System	28 Nov 2020 09:13:36

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-11-28T03:13:31', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '65b0093a-1ad2-4cbc-8736-9bc422d1565a' User entered '28 Nov 2020 03:13:31'	System	28 Nov 2020 09:13:36
	System	28 Nov 2020 09:13:36

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-05T13:41:45', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '63139d10-7d80-4c84-a9ac-5b0690e54ec5' User entered 'No (N)'	System	05 Dec 2020 19:41:55
	System	05 Dec 2020 19:41:55

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-05T13:41:48', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '63139d10-7d80-4c84-a9ac-5b0690e54ec5' User entered 'No (N)'	System	05 Dec 2020 19:41:55
	System	05 Dec 2020 19:41:55

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-05T13:41:52', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '63139d10-7d80-4c84-a9ac-5b0690e54ec5' User entered '05 Dec 2020 13:41:52'	System	05 Dec 2020 19:41:55
	System	05 Dec 2020 19:41:55

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-12T00:02:23', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7c827cf7-5823-4b98-9b41-ba74f4609405' User entered 'No (N)'	System	12 Dec 2020 06:02:37
	System	12 Dec 2020 06:02:37

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-12T00:02:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7c827cf7-5823-4b98-9b41-ba74f4609405' User entered 'No (N)'	System	12 Dec 2020 06:02:37
	System	12 Dec 2020 06:02:37

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-12T00:02:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '7c827cf7-5823-4b98-9b41-ba74f4609405' User entered '12 Dec 2020 00:02:32'	System	12 Dec 2020 06:02:37
	System	12 Dec 2020 06:02:37

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-19T21:50:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77174d32-11ca-48ed-abae-eb464e52b357' User entered 'No (N)'	System	20 Dec 2020 03:51:04
	System	20 Dec 2020 03:51:04

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-19T21:50:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77174d32-11ca-48ed-abae-eb464e52b357' User entered 'No (N)'	System	20 Dec 2020 03:51:04
	System	20 Dec 2020 03:51:04



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-19T21:51:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '77174d32-11ca-48ed-abae-eb464e52b357' User entered '19 Dec 2020 21:51:00'	System	20 Dec 2020 03:51:04
	System	20 Dec 2020 03:51:04

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-27T05:13:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '37679de4-9fbe-4bdf-b29c-c221ec3306c8' User entered 'No (N)'	System	27 Dec 2020 11:13:45
	System	27 Dec 2020 11:13:45

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-27T05:13:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '37679de4-9fbe-4bdf-b29c-c221ec3306c8' User entered 'No (N)'	System	27 Dec 2020 11:13:45
	System	27 Dec 2020 11:13:45

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2020-12-27T05:13:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '37679de4-9fbe-4bdf-b29c-c221ec3306c8' User entered '27 Dec 2020 05:13:41'	System	27 Dec 2020 11:13:45
	System	27 Dec 2020 11:13:45

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-02T00:39:46', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0544df39-1463-433e-913a-660f27cddb95'	System	02 Jan 2021 06:40:00
User entered 'No (N)'	System	02 Jan 2021 06:40:00

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-02T00:39:53', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0544df39-1463-433e-913a-660f27cddb95'	System	02 Jan 2021 06:40:00
User entered 'No (N)'	System	02 Jan 2021 06:40:00

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-02T00:39:57', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0544df39-1463-433e-913a-660f27cddb95' User entered '02 Jan 2021 00:39:57'	System	02 Jan 2021 06:40:00
	System	02 Jan 2021 06:40:00

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:11:31



US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-09T11:55:40', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'c7dfe309-ec4e-406a-8465-721f7a3d13fc' User entered 'No (N)'	System	09 Jan 2021 17:55:49

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-09T11:55:43', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'c7dfe309-ec4e-406a-8465-721f7a3d13fc' User entered 'No (N)'	System	09 Jan 2021 17:55:49
	System	09 Jan 2021 17:55:49

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-09T11:55:47', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'c7dfe309-ec4e-406a-8465-721f7a3d13fc' User entered '09 Jan 2021 11:55:47'	System	09 Jan 2021 17:55:49

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-19T11:33:59', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f1029d11-b0ca-4855-b922-84794807b111'	System	19 Jan 2021 17:34:17
User entered 'No (N)'	System	19 Jan 2021 17:34:17

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-19T11:33:56', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f1029d11-b0ca-4855-b922-84794807b111'	System	19 Jan 2021 17:34:17
User entered 'No (N)'	System	19 Jan 2021 17:34:17



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A308C212-CF2A-4DDE-BC58-04D198E7AE51)', Time: '2021-01-19T11:34:12', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'f1029d11-b0ca-4855-b922-84794807b111' User entered '19 Jan 2021 11:34:12'	System	19 Jan 2021 17:34:17
	System	19 Jan 2021 17:34:17

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-01-27T09:04:26', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9ce8295a-a0ba-4759-9914-3933cd45df49' User entered 'No (N)'	System	27 Jan 2021 15:04:36
	System	27 Jan 2021 15:04:36

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-01-27T09:04:28', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9ce8295a-a0ba-4759-9914-3933cd45df49' User entered 'No (N)'	System	27 Jan 2021 15:04:36
	System	27 Jan 2021 15:04:36

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-01-27T09:04:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '9ce8295a-a0ba-4759-9914-3933cd45df49' User entered '27 Jan 2021 09:04:32'	System	27 Jan 2021 15:04:36
	System	27 Jan 2021 15:04:36

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-02T15:07:20', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd2593c3-2b67-4456-a340-ad75424483a3' User entered 'No (N)'	System	02 Feb 2021 21:07:33
	System	02 Feb 2021 21:07:33

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-02T15:07:24', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd2593c3-2b67-4456-a340-ad75424483a3' User entered 'No (N)'	System	02 Feb 2021 21:07:33
	System	02 Feb 2021 21:07:33

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-02T15:07:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: 'fd2593c3-2b67-4456-a340-ad75424483a3' User entered '02 Feb 2021 15:07:30'	System	02 Feb 2021 21:07:33
	System	02 Feb 2021 21:07:33

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-09T19:38:30', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '137374a4-059d-4150-a556-a8cb6aa6443f' User entered 'No (N)'	System	10 Feb 2021 19:00:52
	System	10 Feb 2021 19:00:52

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-09T19:38:32', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '137374a4-059d-4150-a556-a8cb6aa6443f' User entered 'No (N)'	System	10 Feb 2021 19:00:52
	System	10 Feb 2021 19:00:52

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-09T19:38:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '137374a4-059d-4150-a556-a8cb6aa6443f' User entered '09 Feb 2021 19:38:37'	System	10 Feb 2021 19:00:52
	System	10 Feb 2021 19:00:52

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-13T01:37:33', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8c4e6862-81c6-4f29-b053-42fe25c2fab5' User entered 'No (N)'	System	13 Feb 2021 07:37:41

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-13T01:37:36', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8c4e6862-81c6-4f29-b053-42fe25c2fab5'	System	13 Feb 2021 07:37:41
User entered 'No (N)'	System	13 Feb 2021 07:37:41



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-13T01:37:39', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '8c4e6862-81c6-4f29-b053-42fe25c2fab5' User entered '13 Feb 2021 01:37:39'	System	13 Feb 2021 07:37:41
	System	13 Feb 2021 07:37:41

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-22T07:26:34', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3de81c07-a39c-478d-8e4d-c0d266f31bd0' User entered 'No (N)'	System	22 Feb 2021 13:26:46
	System	22 Feb 2021 13:26:46

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-22T07:26:37', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3de81c07-a39c-478d-8e4d-c0d266f31bd0' User entered 'No (N)'	System	22 Feb 2021 13:26:46

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-02-22T07:26:41', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3de81c07-a39c-478d-8e4d-c0d266f31bd0' User entered '22 Feb 2021 07:26:41'	System	22 Feb 2021 13:26:46
	System	22 Feb 2021 13:26:46

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-01T12:34:30-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5af0c3dd-46ae-4b17-9c58-9b27cfcdd49f'	System	01 Mar 2021 18:34:39
User entered 'No (N)'	System	01 Mar 2021 18:34:39

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-01T12:34:33-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5af0c3dd-46ae-4b17-9c58-9b27cfcdd49f' User entered 'No (N)'	System	01 Mar 2021 18:34:39

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-01T12:34:36-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '5af0c3dd-46ae-4b17-9c58-9b27cfcdd49f' User entered '01 Mar 2021 12:34:36'	System	01 Mar 2021 18:34:39
	System	01 Mar 2021 18:34:39

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-06T11:56:43-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '764fa4d2-1a1d-4a3f-833f-a51f7cd63b45'	System	06 Mar 2021 17:57:02
User entered 'No (N)'	System	06 Mar 2021 17:57:02

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-06T11:56:53-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '764fa4d2-1a1d-4a3f-833f-a51f7cd63b45'	System	06 Mar 2021 17:57:02
User entered 'No (N)'	System	06 Mar 2021 17:57:02

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-06T11:56:58-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '764fa4d2-1a1d-4a3f-833f-a51f7cd63b45'	System	06 Mar 2021 17:57:02
User entered '06 Mar 2021 11:56:58'	System	06 Mar 2021 17:57:02

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-13T01:18:51-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2837731b-5fd1-42ad-af8d-a5f237f05060'	System	13 Mar 2021 07:19:00
User entered 'No (N)'	System	13 Mar 2021 07:19:00

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-13T01:18:52-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2837731b-5fd1-42ad-af8d-a5f237f05060'	System	13 Mar 2021 07:19:00
User entered 'No (N)'	System	13 Mar 2021 07:19:00



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-13T01:18:56-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2837731b-5fd1-42ad-af8d-a5f237f05060'	System	13 Mar 2021 07:19:00
User entered '13 Mar 2021 01:18:56'	System	13 Mar 2021 07:19:00

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-23T15:22:45-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0178eb3c-5d81-4975-bc91-9c423263be53'	System	23 Mar 2021 20:22:56
User entered 'No (N)'	System	23 Mar 2021 20:22:56

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-23T15:22:47-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0178eb3c-5d81-4975-bc91-9c423263be53'	System	23 Mar 2021 20:22:56
User entered 'No (N)'	System	23 Mar 2021 20:22:56

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-23T15:22:51-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0178eb3c-5d81-4975-bc91-9c423263be53'	System	23 Mar 2021 20:22:56
User entered '23 Mar 2021 15:22:51'	System	23 Mar 2021 20:22:56

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-27T08:31:07-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0f5bce3d-0a96-4674-8eab-85c5fd5e31d8'	System	27 Mar 2021 13:31:51
User entered 'Yes (Y)'	System	27 Mar 2021 13:31:51

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-27T08:31:13-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0f5bce3d-0a96-4674-8eab-85c5fd5e31d8'	System	27 Mar 2021 13:31:51
User entered 'No (N)'	System	27 Mar 2021 13:31:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-27T08:31:20-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0f5bce3d-0a96-4674-8eab-85c5fd5e31d8'	System	27 Mar 2021 13:31:51
User entered 'No (N)'	System	27 Mar 2021 13:31:51

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-27T08:31:35-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0f5bce3d-0a96-4674-8eab-85c5fd5e31d8'	System	27 Mar 2021 13:31:51
User entered 'No (N)'	System	27 Mar 2021 13:31:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-27T08:31:47-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '0f5bce3d-0a96-4674-8eab-85c5fd5e31d8' User entered '27 Mar 2021 08:31:47'	System	27 Mar 2021 13:31:51
	System	27 Mar 2021 13:31:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-06T15:02:33-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '814744ef-1fe0-4895-95ce-b471ace744a2'	System	06 Apr 2021 20:02:51
User entered 'No (N)'	System	06 Apr 2021 20:02:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-06T15:02:38-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '814744ef-1fe0-4895-95ce-b471ace744a2'	System	06 Apr 2021 20:02:51
User entered 'No (N)'	System	06 Apr 2021 20:02:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-06T15:02:42-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '814744ef-1fe0-4895-95ce-b471ace744a2'	System	06 Apr 2021 20:02:51
User entered '06 Apr 2021 15:02:42'	System	06 Apr 2021 20:02:51

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-12T12:17:08-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2b7ec7bb-d3a5-4f2f-85bc-d3c69f8cb8aa'	System	12 Apr 2021 17:22:56
User entered 'No (N)'	System	12 Apr 2021 17:22:56

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-12T12:17:10-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2b7ec7bb-d3a5-4f2f-85bc-d3c69f8cb8aa'	System	12 Apr 2021 17:22:56
User entered 'No (N)'	System	12 Apr 2021 17:22:56

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-12T12:17:14-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '2b7ec7bb-d3a5-4f2f-85bc-d3c69f8cb8aa'	System	12 Apr 2021 17:22:56
User entered '12 Apr 2021 12:17:14'	System	12 Apr 2021 17:22:56

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-17T02:53:13-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '61a6e4f2-c1b1-4fbe-9a43-824c090df062'	System	17 Apr 2021 07:53:20
User entered 'No (N)'	System	17 Apr 2021 07:53:20

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-17T02:53:15-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '61a6e4f2-c1b1-4fbe-9a43-824c090df062'	System	17 Apr 2021 07:53:20
User entered 'No (N)'	System	17 Apr 2021 07:53:20



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-17T02:53:18-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '61a6e4f2-c1b1-4fbe-9a43-824c090df062'	System	17 Apr 2021 07:53:20
User entered '17 Apr 2021 02:53:18'	System	17 Apr 2021 07:53:20

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-24T18:29:29-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '69999b1c-d2c4-4bd1-be21-e98db85cdf0f' User entered 'No (N)'	System	24 Apr 2021 23:29:38
	System	24 Apr 2021 23:29:38

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Have you been exposed to someone with 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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-24T18:29:31-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '69999b1c-d2c4-4bd1-be21-e98db85cdf0f' User entered 'No (N)'	System	24 Apr 2021 23:29:38
	System	24 Apr 2021 23:29:38

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-04-24T18:29:35-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '69999b1c-d2c4-4bd1-be21-e98db85cdf0f' User entered '24 Apr 2021 18:29:35'	System	24 Apr 2021 23:29:38
	System	24 Apr 2021 23:29:38

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-05-03T12:24:35-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '995c28df-2d9b-4a73-ae3f-70cc63d5acfe'	System	03 May 2021 17:24:55
User entered 'No (N)'	System	03 May 2021 17:24:55

US3292339

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:35:15

Have you been exposed to someone with 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 (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-05-03T12:24:38-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '995c28df-2d9b-4a73-ae3f-70cc63d5acfe' User entered 'No (N)'	System	03 May 2021 17:24:55
	System	03 May 2021 17:24:55

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (238021EC-05EB-4D90-82D8-6256B979EE0B)', Time: '2021-05-03T12:24:41-05:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '995c28df-2d9b-4a73-ae3f-70cc63d5acfe' User entered '03 May 2021 12:24:41'	System	03 May 2021 17:24:55
	System	03 May 2021 17:24:55

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:11:31

**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:11:31



**US3292339**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:35:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:11:31
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:11:31

US3292339

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:35:15**

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 23:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-01T12:34:44-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3b965b51-5cca-47bc-a79a-68b9c3a5334a'	System	05 Mar 2021 17:22:01
User entered 'No (N)'	System	05 Mar 2021 17:22:01

US3292339

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:35:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05BDC3B0-C172-4006-A564-F45511FAA07F)', Time: '2021-03-01T12:34:48-06:00', User OID: 'PatientReportedOutcome (US3292339)', ODM File OID: '3b965b51-5cca-47bc-a79a-68b9c3a5334a' User entered '01 Mar 2021 12:34:48'	System	05 Mar 2021 17:22:01
	System	05 Mar 2021 17:22:01

US3292339

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:13:41

US3292339

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '25 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:13:41

US3292339

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:13:41

US3292339

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:13:41

US3292339

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:13:46



US3292339

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:51:39
User entered 'l'	System	01 Dec 2020 16:13:46

**US3292339**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:50:36

**US3292339**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '30 Dec 2020'	(b) (4), (b) (6)	27 Jan 2021 18:50:36

**US3292339**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Jan 2021 18:50:36

US3292339

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:50:36

US3292339

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:51:09

**US3292339**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:35:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User entered 'l'	System	27 Jan 2021 18:51:09

**US3292339**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:53:35



**US3292339**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:53:35

**US3292339**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Jan 2021 18:53:35

US3292339

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:53:35

US3292339

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:12:29

**US3292339**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:35:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User entered 'l'	System	27 Jan 2021 19:12:29

US3292339

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 14:34:28

**US3292339**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 14:34:28

US3292339

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Mar 2021 14:34:28



US3292339

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 14:34:28

US3292339

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 14:34:41

US3292339

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:57:56
User entered 'l'	System	02 Mar 2021 14:34:41

US3292339

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:31:21

US3292339

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:31:21

US3292339

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Mar 2021 17:31:21

US3292339

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered 'VISIT4'	System	25 Mar 2021 17:31:21

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:18:43



US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered empty.	System	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

**US3292339**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

**US3292339**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered empty.	System	31 Mar 2021 19:18:43



US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered empty.	System	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered empty.	System	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered empty.	System	31 Mar 2021 19:18:43

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24

US3292339

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24



US3292339

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 17:31:25

**US3292339**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:35:15**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:31:25

US3292339

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:31:36

US3292339

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:31:36

US3292339

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '10:11'	(b) (4), (b) (6)	25 Mar 2021 17:31:36

US3292339

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered '25 Mar 2021 10:11'	System	25 Mar 2021 17:31:36

US3292339

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:31:40

US3292339

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:24:24
User entered 'I'	System	25 Mar 2021 17:31:40



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:21:35

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:21:35

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 15:21:35

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 15:21:35

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

**US3292339**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:35:15**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Dawn Killian (b) (4)	23 Apr 2021 07:56:09
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:07:36

**US3292339**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:35:15**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User closed query 'Per sponsor review, 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).		26 Apr 2021 15:01:32
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
Query 'Per sponsor review, 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) Dawn Killian (b) (4)	23 Apr 2021 07:56:32
User entered 'Amendment 6 or later (Amendment 6 or later)'	Dawn Killian (b) (4)	23 Apr 2021 07:56:09
User opened query 'Per sponsor review, 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)	22 Apr 2021 04:53:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:07:36



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'I'	System	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:35:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'I'	System	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	22 Jan 2021 15:23:11
DataPoint set to visible.	System	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	22 Jan 2021 15:23:11
DataPoint set to visible.	System	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User accepted default value 'Pre-Dose (PREDOSE)'		22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	22 Jan 2021 15:23:21
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:23:21
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Jan 2021 15:23:11
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:23:11



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '09:55'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '21 Jan 2021 09:55'	System	22 Jan 2021 15:23:21
User entered '22 Jan 2021 09:55'	System	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.7' C	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '90'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'bpm'	System	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '17'	(b) (4), (b) (6)	22 Jan 2021 15:23:11



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'breaths/min'	System	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '136'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '77'	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 15:23:11

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	22 Jan 2021 15:23:11
DataPoint set to visible.	System	22 Jan 2021 15:22:19



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User accepted default value 'Post-Dose (POSTDOSE)'		22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '12:00'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '21 Jan 2021 12:00'	System	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '36.3' C	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:23:59



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '85'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'bpm'	System	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '15'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'breaths/min'	System	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '143'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '76'	(b) (4), (b) (6)	22 Jan 2021 15:23:59

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	22 Jan 2021 15:23:59



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:24:07

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:24:07

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mRNA-1273'	System	22 Jan 2021 15:24:33
DataPoint set to visible.	System	22 Jan 2021 15:22:19

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '11:29'	(b) (4), (b) (6)	22 Jan 2021 15:24:33



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '21 Jan 2021 11:29'	System	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'ONCE'	System	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 15:24:33

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:24:49

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:24:49

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '10:02'	(b) (4), (b) (6)	22 Jan 2021 15:24:49

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '21 Jan 2021 10:02'	System	22 Jan 2021 15:24:49



US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:25:06

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 15:25:06

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '10:34'	(b) (4), (b) (6)	22 Jan 2021 15:25:06

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:35:15

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '21 Jan 2021 10:34'	System	22 Jan 2021 15:25:06

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:25:13

US3292339

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'I'	System	22 Jan 2021 15:25:13

US3292339

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	01 Feb 2021 16:26:21

US3292339

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '28 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	01 Feb 2021 16:26:21



US3292339

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	01 Feb 2021 16:26:21

US3292339

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	01 Feb 2021 16:26:21

US3292339

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	01 Feb 2021 16:26:24

US3292339

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'l'	System	01 Feb 2021 16:26:24

US3292339

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'I'	System	01 Feb 2021 16:26:24
DataPoint set to visible.	System	01 Feb 2021 16:26:24

**US3292339**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 18:21:23

US3292339

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:21:23

US3292339

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Feb 2021 18:21:23



**US3292339**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'OLD29'	System	26 Feb 2021 18:21:23

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User accepted default value 'Pre-Dose (PREDOSE)'		26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

**US3292339**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '08:53'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '26 Feb 2021 08:53'	System	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '36.2' C	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 18:22:12



US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '91'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'bpm'	System	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '16'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'breaths/min'	System	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '149'	(b) (4), (b) (6)	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '79'	(b) (4), (b) (6)	26 Feb 2021 18:22:12



US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	26 Feb 2021 18:22:12

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User accepted default value 'Post-Dose (POSTDOSE)'		26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

**US3292339**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '11:07'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '26 Feb 2021 11:07'	System	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '36.3' C	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 18:22:58



US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '80'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'bpm'	System	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '16'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'breaths/min'	System	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '164'	(b) (4), (b) (6)	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '81'	(b) (4), (b) (6)	26 Feb 2021 18:22:58



US3292339

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mmHg'	System	26 Feb 2021 18:22:58

US3292339

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 18:23:13

US3292339

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:23:13

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'mRNA-1273'	System	26 Feb 2021 20:31:15
DataPoint set to visible.	System	01 Feb 2021 16:26:24

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:15



US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '10:37'	(b) (4), (b) (6)	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '26 Feb 2021 10:37'	System	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	(b) (4), (b) (6)
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Subject prefer right arm' (Site from System).		01 Mar 2021 13:03:05
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		26 Feb 2021 20:31:40
User entered 'Right Arm (RIGHT ARM)'	System	26 Feb 2021 20:31:15
	(b) (4), (b) (6)	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'ONCE'	System	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:35:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 20:31:15

US3292339

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:31:48

US3292339

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'l'	System	26 Feb 2021 20:31:48

**US3292339**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:35:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Mar 2021 13:29:27



US3292339

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '5 Mar 2021'	(b) (4), (b) (6)	06 Mar 2021 13:29:27

US3292339

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Mar 2021 13:29:27

US3292339

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:35:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	06 Mar 2021 13:29:27

US3292339

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Mar 2021 13:29:31

US3292339

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'l'	System	06 Mar 2021 13:29:31

**US3292339**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:32:12

**US3292339**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:35:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:32:12

US3292339

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Mar 2021 17:32:12



US3292339

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered 'OLD57'	System	25 Mar 2021 17:32:12

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

**US3292339**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

**US3292339**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20



**US3292339**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

**US3292339**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:35:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:20

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered empty.	System	25 Mar 2021 17:32:20



US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48

US3292339

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:35:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48

US3292339

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 17:32:25

US3292339

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:32:25

US3292339

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:32:49

US3292339

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:32:49

**US3292339**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:35:15**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:44:04
User entered '10:11'	(b) (4), (b) (6)	25 Mar 2021 17:32:49

US3292339

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:15:48
User entered '25 Mar 2021 10:11'	System	25 Mar 2021 17:32:49



US3292339

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:35:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:35
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).		26 Apr 2021 10:56:29
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'AE log updated' (Site from DM).	Antonio Gutierrez (b) (4)	23 Apr 2021 16:48:41
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:46:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:46:10
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:07:14

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	21 Oct 2020 20:29:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:17
User entered	System	20 Sep 2020 18:14:13
'USA-US072-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 18:14:13

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:57:26
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'As per discharge diagnosis, not caused by underlying medical condition. Discharge diagnosis states "Angioedema due to Lisinopril.'" (Site from DM).	Antonio Gutierrez (b) (4)	03 Nov 2020 17:42:59
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:57:20
DataPoint Verified.		21 Oct 2020 20:29:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:38:41
Data point term sent to Coder	System	18 Sep 2020 21:38:00
User entered 'Angioedema'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '16 Sep 2020'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '18 Sep 2020'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

Severity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	21 Oct 2020 20:29:56
User closed query 'PV Query: The event intensity is "Grade 4" for this event of angioedema. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 11:43:51
Query 'PV Query: The event intensity is "Grade 4" for this event of angioedema. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' answered with 'this has been added' (Site from Safety).	Antonio Gutierrez (b) (4)	30 Sep 2020 22:29:45
User opened query 'PV Query: The event intensity is "Grade 4" for this event of angioedema. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:54:30
User entered 'Grade 4 (Grade 4)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25



US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	30 Sep 2020 22:29:31
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'I'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '18 Sep 2020'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'l'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25



US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:41:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'will update fields' (Site from DM). User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:48:22
User entered '0' reason for change: New Information	System	03 Nov 2020 17:43:46
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). DataPoint Verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:43:46
User entered '1'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:57:05
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:48:44
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	03 Nov 2020 17:48:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:00:16
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'action taken updated' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:51:50
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 16:51:26
User entered '0' reason for change: New Information	(b) (4), (b) (6)	18 Feb 2021 16:51:26
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:57:08
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:48:44
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	03 Nov 2020 17:48:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:04:27
User closed query 'PV Query: Please clarify if lisinopril was discontinued. If so, please update conmed page accordingly.' (Site from Safety).		04 Nov 2020 15:29:37
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		04 Nov 2020 15:29:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		04 Nov 2020 15:29:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Narrative updated' (Site from Safety).	Antonio Gutierrez (b) (4)	03 Nov 2020 20:34:07
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 20:33:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED SITE OF HOSPITALIZATION IN THE ICU DUE TO ALLERGIC REACTION TO LISINOPRIL. HE STATED THAT HE WAS TAKEN TO THE HOSPITAL AFTER MIDNIGHT, EARLY MORNING OF 17SEP2020, AFTER EXPERIENCING A 2 HOUR EPISODE OF PERSISTENT COUGHING. HE REPORTED THAT EMS WAS CALLED AFTER HE HAD NOTED SEVERE SWELLING OF HIS NECK AND DIFFICULTY BREATHING. AS PER SUBJECT, HE CANNOT RECALL WHAT MEDICATIONS HE WAS GIVEN WHILE INPATIENT, NOR THE PRESCRIPTION HE RECEIVED. HE STATES THAT HE WAS RELEASED MORNING OF 18SEP2020 WITH A DIAGNOSIS OF ANGIOEDEMA CAUSED BY AN ALLERGIC REACTION TO LISINOPRIL. MEDICAL RECORDS WILL BE REQUESTED ASAP AND UPDATES TO THIS REPORT WILL BE SUBMITTED. UPDATE 03NOV2020: Diagnostic test results. Chest Xray showed no acute cardiopulmonary findings. CT Maxillofacial with Contrast showed: "Extensive laryngeal edema with markedly thickened epiglottis, prevertebral soft tissue thickening, and extensive edema at the base of the tongueand in the submandibular space. Appearance most suggestive of angioedema or allergic reaction. No soft tissue gas or drainable abscess to suggest infection. There is narrowing of the airway but the airway appears patent at this time.'" reason for change: New Information	Antonio Gutierrez (b) (4)	03 Nov 2020 20:33:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ConMeds and ConProc will be updated' (Site from Safety).	Antonio Gutierrez (b) (4)	03 Nov 2020 17:54:20

US3292339

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify if lisinopril was discontinued. If so, please update conmed page accordingly.' answered with 'Lisinopril was indeed discontinued. Will update conmed log' (Site from Safety).	Antonio Gutierrez (b) (4)	03 Nov 2020 17:28:42
User opened query 'PV Query: Please clarify if lisinopril was discontinued. If so, please update conmed page accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 14:02:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 14:02:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 14:02:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User closed query 'PV Query: Please report if the patient had exposure to any potential triggers (ie. food, cosmetics, environmental, etc.), other than lisinopril.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:48:03
User closed query 'PV Query: Other than the reported seasonal allergies, please report if the patient has any known allergies or prior allergic reactions.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:47:58
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:47:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:46:59

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:46:51
User closed query 'PV Query: Please confirm that the subject did not have prior urticaria, rash, pruritus or other allergic signs/symptoms after dose one of study medication.' (Site from Safety).		20 Oct 2020 19:46:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medical records were requested and can be scanned and sent redacted. Please respond to (b) (4)' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:17:53
Query 'PV Query: Other than the reported seasonal allergies, please report if the patient has any known allergies or prior allergic reactions.' answered with 'Pt states that he has no known allergies or prior allergic reactions other than seasonal allergies. Pt also states that back in April of 2019, he now thinks he may have had a very minor episode of an allergic reaction based on what he experienced this time. However, he states he is not sure, it is simply a guess. No medical treatment was ever sought for the 2019 episode and no medication taken at that time. Whatever the event was, it resolved on its own.' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:17:09
Query 'PV Query: Please report if the patient had exposure to any potential triggers (ie. food, cosmetics, environmental, etc.), other than lisinopril.' answered with 'Pt cannot identify any other potential triggers other than Lisinopril.' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:09:45
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Can records be deidentified and emailed to Moderna Safety? Please respond to (b) (4)' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:09:08

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No COVID-19 testing as per patient and inpatient medical records.' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:07:53
Query 'PV Query: Please confirm that the subject did not have prior urticaria, rash, pruritus or other allergic signs/symptoms after dose one of study medication.' answered with 'Confirmed; no prior urticaria, rash, pruritus or other allergic signs/symptoms after dose one of study medication.' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Oct 2020 21:07:22
User opened query 'PV Query: Please report if the patient had exposure to any potential triggers (ie. food, cosmetics, environmental, etc.), other than lisinopril.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:55:04
User opened query 'PV Query: Other than the reported seasonal allergies, please report if the patient has any known allergies or prior allergic reactions.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:54:53
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:54:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:53:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:52:30
User opened query 'PV Query: Please confirm that the subject did not have prior urticaria, rash, pruritus or other allergic signs/symptoms after dose one of study medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 17:52:20

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject notified site of hospitalization in the ICU due to allergic reaction to Lisinopril. He stated that he was taken to the hospital after midnight, early morning of 17SEP2020, after experiencing a 2 hour episode of persistent coughing. He reported that EMS was called after he had noted severe swelling of his neck and difficulty breathing. As per subject, he cannot recall what medications he was given while inpatient, nor the prescription he received. He states that he was released morning of 18SEP2020 with a diagnosis of Angioedema caused by an allergic reaction to Lisinopril. Medical records will be requested asap and updates to this report will be submitted.'	Antonio Gutierrez (b) (4)	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Sep 2020 21:37:25



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 21:37:25

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:35:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
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)	20 Oct 2020 17:36:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:36:36
Data point term sent to Coder	System	20 Oct 2020 17:36:00
User entered 'Urinary Tract Infection'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '1 Oct 2020'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Oct 2020 10:26:06
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Kevin Martinez (b) (4)	20 Oct 2020 17:36:29
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 17:36:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Oct 2020 17:36:17
User entered empty; reason for change Data Entry Error	System	20 Oct 2020 17:36:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kevin Martinez (b) (4)	20 Oct 2020 17:36:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 17:36:07
User entered 'un:un' (non-conformant).	System	20 Oct 2020 17:36:07
User opened query 'Data is required. Please provide.' (Site from System).	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53
User entered empty.	System	20 Oct 2020 17:35:53
	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User entered empty.	System	20 Oct 2020 17:36:17
User entered '1 Oct 2020 UN:UN' (non-conformant).	System	20 Oct 2020 17:36:07
User entered empty.	System	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:28:33
DataPoint Un-verified.	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:28:35
DataPoint Un-verified.	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
User entered '20 Oct 2020' reason for change: Data Entry Error	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 22:36:28
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Dawn Killian (b) (4)	04 Nov 2020 19:10:21
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 19:10:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User entered empty.	System	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53



US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53



US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Not Related (NOT RELATED)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Not Related (NOT RELATED)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'None (NONE)'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 and 12 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:48:20
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 and 12 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	28 Dec 2020 16:37:18
DataPoint Un-verified.	(b) (4)	28 Dec 2020 16:37:13
User entered '0' reason for change: Data Entry Error	Kevin Martinez (b) (4)	28 Dec 2020 16:37:13
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 and 12 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:57:43
DataPoint Verified.		21 Oct 2020 20:29:56
User entered '1'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Un-verified.	(b) (4)	
	Kevin Martinez (b) (4)	28 Dec 2020 16:37:13
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Kevin Martinez (b) (4)	28 Dec 2020 16:37:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53
	(b) (4)	

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered '0'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53



US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:28:45
DataPoint Un-verified.	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Dawn Killian (b) (4)	04 Nov 2020 19:10:11
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53
	(b) (4)	

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[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 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:29:56
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:35:53

US3292339

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:35:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User entered '0'	System	20 Oct 2020 17:35:53

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14
User entered 'I'	System	20 Oct 2020 17:35:53

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:36:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:36:25
Data point term sent to Coder	System	03 Nov 2020 20:35:27
User entered 'Injection Site Pain'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04



US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '12 Oct 2020'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User entered empty.	System	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '20 Oct 2020'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User entered empty.	System	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04



US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Not Related (NOT RELATED)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Related (RELATED)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04



US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'None (NONE)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'l'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

US3292339

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:35:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[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 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User entered '0'	System	03 Nov 2020 20:35:04



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19
User entered '0'	System	03 Nov 2020 20:35:04

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:19

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	06 Nov 2020 19:29:52
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:09:47

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site hypoaesthesia, LLT: Injection site numbness - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:53:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:53:25
Data point term sent to Coder	System	03 Nov 2020 20:37:31
User entered 'Injection Site Numbness'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).		05 Nov 2020 13:09:43
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'updated' (Site from Safety).	Dawn Killian (b) (4)	04 Nov 2020 19:11:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4)	04 Nov 2020 19:10:52
	(b) (4)	
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:30:18
User entered 'Yes (Y)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '16 Oct 2020'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User entered empty.	System	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Yes (Y)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45
	(b) (4)	

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
	(b) (4)	
User entered '30 Dec 2020' reason for change: New Information	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45
	(b) (4)	

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User entered empty.	System	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'No (N)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Not Related (NOT RELATED)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Not Related (NOT RELATED)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'None (NONE)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'l'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

US3292339

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered '0'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Un-verified.	(b) (4)	
	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Gerardo Pena (b) (4)	29 Jan 2021 20:12:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Dawn Killian (b) (4)	03 Nov 2020 20:36:45
	(b) (4)	

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[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 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:29:52
User entered empty.	Dawn Killian (b) (4)	03 Nov 2020 20:36:45

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User entered '0'	System	03 Nov 2020 20:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:35:15

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24
User entered '0'	System	03 Nov 2020 20:36:45

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:24

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
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)	22 Jan 2021 16:05:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 16:05:01
Data point term sent to Coder	System	22 Jan 2021 16:03:49
User entered 'Urinary Tract Infection'	(b) (4), (b) (6)	22 Jan 2021 16:03:29



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

US3292339

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '1 Nov 2020'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User entered empty.	System	22 Jan 2021 16:03:29

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '19 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:03:29



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User entered empty.	System	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

US3292339

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

US3292339

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29



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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:03:39
User entered 'None (NONE)' reason for change: Data Entry Error	System	22 Jan 2021 16:03:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 16:03:29
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:35:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'l'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

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 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 16:03:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:35:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User entered '0'	System	22 Jan 2021 16:03:29



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29
User entered 'I'	System	22 Jan 2021 16:03:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:29

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:45:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 16:45:10
Data point term sent to Coder	System	23 Apr 2021 16:44:25
User entered 'Fatigue (reactogenicity)'	Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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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 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '2 Oct 2020'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14



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Generated On: 09 Jun 2021 16:35:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Apr 2021 16:44:31
User entered '20:13' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:31
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Apr 2021 16:44:14
User entered empty.	Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User entered '2 Oct 2020 20:13'	System	23 Apr 2021 16:44:31
User entered empty.	System	23 Apr 2021 16:44:14

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '9 Oct 2020'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Apr 2021 16:44:31
User entered '22:20' reason for change: Data Entry Error	System	23 Apr 2021 16:44:31
User entered '22:20' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Apr 2021 16:44:14
User entered empty.	System	23 Apr 2021 16:44:14
	Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User entered '9 Oct 2020 22:20'	System	23 Apr 2021 16:44:31
User entered empty.	System	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14



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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Related (RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'l'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14



**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[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 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	23 Apr 2021 16:44:14

US3292339

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:35:15

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User entered '0'	System	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34
User entered '0'	System	23 Apr 2021 16:44:14

**US3292339**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:15:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:35:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:36
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:04
User closed query 'Per ETRTR: Upon receipt of Medical Records, please ensure updating Medication and dose given for SAE Angioedema, thanks.' (Site from CRA).		16 Oct 2020 17:13:52
Query 'Per ETRTR: Upon receipt of Medical Records, please ensure updating Medication and dose given for SAE Angioedema, thanks.' answered with 'updated' (Site from CRA).	Victoria Hernandez (b) (4)	29 Sep 2020 14:27:45
User opened query 'Per ETRTR: Upon receipt of Medical Records, please ensure updating Medication and dose given for SAE Angioedema, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 21:12:38
User entered 'Yes (Y)'		28 Aug 2020 18:29:06

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:24:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:24:35
Data point term sent to Coder	System	28 Aug 2020 18:32:48
User entered 'fish oil'	(b) (4), (b) (6)	28 Aug 2020 18:32:26



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 20:03:09
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:08
DataPoint Un-verified.	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:05
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 17:01:32
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'nutritional suppliment'	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '2000'	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 21:43:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 21:43:38
User entered 'mg (mg)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 21:43:38
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 18:32:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:32:26



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:32:26

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'un UNK 2010'		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:32:26

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Aug 2020 18:32:26

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:32:26



**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:32:26

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:34:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:34:41
Data point term sent to Coder	System	28 Aug 2020 18:33:50
User entered 'vitamin d3'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 20:11:14
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:24
DataPoint Un-verified.	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:19
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 17:01:41
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'nutritional suppliment'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '25'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).		07 Oct 2020 14:04:39
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 00:19:56
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:34:29
User entered 'mg (mg)'		28 Aug 2020 18:33:12

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'three times daily (TID)'	(b) (4), (b) (6)	28 Aug 2020 18:33:12



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'		28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:33:12



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Aug 2020 18:33:12

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:33:12

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:33:12

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:59:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:59:39
Data point term sent to Coder	System	28 Aug 2020 18:33:50
User entered 'vitamin c'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:11:34
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	28 Dec 2020 16:28:35
DataPoint Un-verified.	Kevin Martinez (b) (4)	28 Dec 2020 16:28:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Kevin Martinez (b) (4)	28 Dec 2020 16:28:31
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 17:01:51
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Nutritional suppliment'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '1000'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 18:33:42



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'		28 Aug 2020 18:33:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'		28 Aug 2020 18:33:42



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:33:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:33:42

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Aug 2020 18:33:42

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:33:42

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:33:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
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)	24 Sep 2020 00:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:18:38
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4) (b) (4)	24 Sep 2020 00:17:52 24 Sep 2020 00:17:39
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)	28 Aug 2020 21:07:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:07:39
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	28 Aug 2020 18:34:52 28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 20:12:00
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:48
DataPoint Un-verified.	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	28 Dec 2020 16:28:44
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 17:02:43
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. Otherwise, confirm if the indication should be updated (i.e. Heart health).' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Nov 2020 17:02:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. Otherwise, confirm if the indication should be updated (i.e. Heart health).' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 00:17:44
User entered 'heart health' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 00:17:39
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. Otherwise, confirm if the indication should be updated (i.e. Heart health).' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:57:16
User entered 'Nutritional supplement'		28 Aug 2020 18:34:48



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '325'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'un UNK 2010'		28 Aug 2020 18:34:48



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'		28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:34:48

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:34:48

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:34:48

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:36:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:36:48
Data point term sent to Coder User entered 'Janumet'	System (b) (4), (b) (6)	28 Aug 2020 18:35:53 28 Aug 2020 18:35:30



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Type 2 diabetes'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '50/1000'		28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'		28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:35:30



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un Apr 2020'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 18:35:30

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:35:30



**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:35:30

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: ANTIVIRALS, PRODUCT: ACICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:15:57
Data point term sent to Coder	System	28 Aug 2020 18:38:59
User entered 'Aciclovir'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'varicella'		28 Aug 2020 18:38:05

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '200'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'as needed (PRN)'		28 Aug 2020 18:38:05



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:38:05

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un UNK 2010'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'		28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:05



**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:38:05

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 18:38:05

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
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)	28 Aug 2020 18:39:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:39:41
Data point term sent to Coder User entered 'lisinopril'	System (b) (4), (b) (6)	28 Aug 2020 18:38:59 28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'hypertension'		28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '5'		28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'		28 Aug 2020 18:38:45



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'		28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'un UNK 2018'		28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:07:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:29:35
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	03 Nov 2020 17:29:35
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'		28 Aug 2020 18:38:45



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:07:29
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	03 Nov 2020 17:29:35
User entered '17 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	03 Nov 2020 17:29:35
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:38:45

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User entered 'I'	System	28 Aug 2020 18:38:45

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User entered 'I'	System	28 Aug 2020 18:38:45

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:53
User entered '804 (804)'	System	28 Aug 2020 18:38:45

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:35:36
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 Aug 2020 07:35:36
Data point term sent to Coder	System	28 Aug 2020 18:40:02
User entered 'montelukast'	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:39:39

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'seasonal allergy'		28 Aug 2020 18:39:39



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered '10'	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'		28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:39:39

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Aug 2020 18:39:39



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'		28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Un-verified.	(b) (4)	22 Jan 2021 15:45:04
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 15:45:04
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'Yes (Y)'		28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Un-verified.	(b) (4)	22 Jan 2021 15:45:04
User entered '1 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 15:45:04
DataPoint Verified.		21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User signature succeeded.	Douglas Denham (b) (4) (h) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:39:39

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User entered 'I'	System	28 Aug 2020 18:39:39

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User entered 'I'	System	28 Aug 2020 18:39:39

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:19:58
User entered '804 (804)'	System	28 Aug 2020 18:39:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: PIRFENIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:14:39
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 Aug 2020 07:14:39
Data point term sent to Coder	System	28 Aug 2020 18:42:05
User entered 'pirfenidone'	(b) (4), (b) (6)	28 Aug 2020 18:41:33



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'		28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'idiopathic pulmonary fibrosis'	(b) (4), (b) (6)	28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '801'		28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'three times daily (TID)'		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Aug 2020 18:41:33



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'un Jan 2020'	(b) (4), (b) (6)	28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.		28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	21 Oct 2020 20:45:40
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Aug 2020 18:41:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 18:41:33



**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:41:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 07:53:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 07:53:29
Data point term sent to Coder	System	28 Dec 2020 16:37:44
DataPoint Un-verified.	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
Coding entries removed.	(b) (4)	
	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
User entered 'BACTRIM(Trimethoprim / Sulfamethoxazole)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 20:50:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 20:50:27
Data point term sent to Coder	System	15 Oct 2020 20:41:57
User entered 'Bactrim'	Kristy Trevino (b) (4)	15 Oct 2020 20:40:57
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Urinary Tract Infection'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 19:47:52
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	28 Dec 2020 16:36:55
DataPoint Un-verified.	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
User entered '400/80' reason for change: Data Entry Error	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:54:59
DataPoint Verified.		21 Oct 2020 20:45:40
User entered '400'	Kristy Trevino (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kristy Trevino (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'twice daily (BID)'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '14 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please note the corresponding AE that matches this Con Med indication during this time frame has resolved. Please review if the Con Med is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 19:47:32
Query 'Per DM CLR: Please note the corresponding AE that matches this Con Med indication during this time frame has resolved. Please review if the Con Med is still ongoing. ' answered with 'updated' (Site from DM).	Kevin Martinez (b) (4)	28 Dec 2020 16:37:00
DataPoint Un-verified.	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
User entered 'No (N)' reason for change: Data Entry Error	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
User opened query 'Per DM CLR: Please note the corresponding AE that matches this Con Med indication during this time frame has resolved. Please review if the Con Med is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:54:40
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Un-verified.	(b) (4)	
	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	Kevin Martinez (b) (4)	28 Dec 2020 16:36:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 20:45:40
	(b) (4)	
User entered empty.	Kristy Trevino (b) (4)	15 Oct 2020 20:40:57
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	15 Oct 2020 20:40:57



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User entered '2'	System	15 Oct 2020 20:40:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User entered 'I'	System	15 Oct 2020 20:40:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:39
User entered '804 (804)'	System	15 Oct 2020 20:40:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:12:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:12:34
Data point term sent to Coder	System	25 Mar 2021 16:11:15
Coding entries removed.	(b) (4), (b) (6)	25 Mar 2021 16:10:40
DataPoint Verified.		21 Oct 2020 20:45:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 05:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 05:03:28
Data point term sent to Coder	System	20 Oct 2020 17:40:09
User entered 'Mirtazapine'	Kevin Martinez (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM). Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'updated, updated MHx as well' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 09:15:47
User entered 'Depression' reason for change: Data Entry Error		25 Mar 2021 16:11:03
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM). DataPoint Verified.		25 Mar 2021 16:10:40
User entered 'Appetite Booster'	Kevin Martinez (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '15'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '01 Oct 2020'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:39:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 17:39:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 17:39:57

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 17:39:57

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
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)	20 Oct 2020 19:32:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:32:39
Data point term sent to Coder	System	20 Oct 2020 17:41:10
User entered 'Tamsulosin'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Urinary Tract Infection'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '.4'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'mg (mg)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'once daily (QD)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'Oral (ORAL)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '16 Oct 2020'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered '0'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:28:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:48
DataPoint Verified.		05 Nov 2020 16:09:40
DataPoint Un-verified.		27 Oct 2020 14:16:27
User entered 'No (N)' reason for change: Data Entry Error		27 Oct 2020 14:16:27
DataPoint Verified.		21 Oct 2020 20:45:40
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	20 Oct 2020 17:41:07
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:41:06
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:26:29
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 21:26:19
User entered '20 Oct 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	19 Mar 2021 21:26:19
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:18:38
DataPoint Verified.		11 Nov 2020 02:28:39
User closed query 'The Con Meds log has not been updated with a Stop Date. Please verify and update as appropriate.' (Site from CRA).		11 Nov 2020 02:28:34
Query 'The Con Meds log has not been updated with a Stop Date. Please verify and update as appropriate.' answered with 'Conmed log updated.' (Site from CRA).		08 Nov 2020 01:01:10
User opened query 'The Con Meds log has not been updated with a Stop Date. Please verify and update as appropriate.' (Site from CRA).		06 Nov 2020 19:35:37
DataPoint Un-verified.		05 Nov 2020 16:09:50
DataPoint Verified.		05 Nov 2020 16:09:40

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). DataPoint Un-verified.	System	27 Oct 2020 14:16:40
	(b) (4), (b) (6)	27 Oct 2020 14:16:40
User entered '26 Oct 2020' reason for change: Data Entry Error		27 Oct 2020 14:16:40
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). DataPoint Verified.	System	27 Oct 2020 14:16:27
	(b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered empty.	Kevin Martinez (b) (4)	20 Oct 2020 17:41:07
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:45:40
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	20 Oct 2020 17:41:07

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User entered 'I'	System	20 Oct 2020 17:41:07

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User entered 'I'	System	20 Oct 2020 17:41:07

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:47
User entered '804 (804)'	System	20 Oct 2020 17:41:07



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: DIPHENHYDRAMINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:00:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:00:24
Data point term sent to Coder	System	03 Nov 2020 19:19:46
User entered 'Diphenhydramine HCL'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Angioedema'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '25'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:39:43
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:27:19
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 21:27:11
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:52:20
DataPoint Un-verified.		22 Jan 2021 16:00:32

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:00:32
DataPoint Verified.		05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:19:16



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User entered empty.	System	03 Nov 2020 19:19:16

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User entered empty.	System	03 Nov 2020 19:19:16

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:51
User entered empty.	System	03 Nov 2020 19:19:16

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:02:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:02:23
Data point term sent to Coder	System	03 Nov 2020 19:22:49
User entered 'Epinephrine'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Angioedema'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0.4'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:39:50
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:28:01
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 21:27:54
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:52:40
DataPoint Un-verified.		22 Jan 2021 16:00:41

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:00:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:22:46

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User entered empty.	System	03 Nov 2020 19:22:46

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User entered empty.	System	03 Nov 2020 19:22:46

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:54
User entered empty.	System	03 Nov 2020 19:22:46

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:14:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:14:21
Data point term sent to Coder	System	03 Nov 2020 19:24:51
User entered 'Iopamidol'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'CT Contrast'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '100'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'as needed (PRN)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '22 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:24:02

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User entered empty.	System	03 Nov 2020 19:24:02

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User entered empty.	System	03 Nov 2020 19:24:02

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:59
User entered empty.	System	03 Nov 2020 19:24:02



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:03:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:03:16
Data point term sent to Coder	System	03 Nov 2020 19:35:04
User entered 'Famotidine'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Angioedema'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '20'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:34:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User entered empty.	System	03 Nov 2020 19:34:42



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User entered empty.	System	03 Nov 2020 19:34:42

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:02
User entered empty.	System	03 Nov 2020 19:34:42

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:18:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 05:18:19
Data point term sent to Coder	System	03 Nov 2020 19:38:18
User entered 'Methylprednisolone'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Angioedema'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '125'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'once daily (QD)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:40
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:39:57
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:28:52
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 21:28:46
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:53:53
DataPoint Un-verified.		22 Jan 2021 16:01:01
User entered 'Yes (Y)' reason for change: Data Entry Error		22 Jan 2021 16:01:01
DataPoint Verified.		05 Nov 2020 16:09:40

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:37:51

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User entered 'I'	System	03 Nov 2020 19:37:51

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User entered 'I'	System	03 Nov 2020 19:37:51

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:05
User entered '804 (804)'	System	03 Nov 2020 19:37:51

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 11:42:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 11:42:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:31:12
Data point term sent to Coder	System	09 Nov 2020 15:53:52
User entered 'Medrol Dose Pack'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered 'Angioedema'	(b) (4), (b) (6)	09 Nov 2020 15:53:04



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered '4'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:31:12
User entered 'mg (mg)'		09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered 'other (OTHER)'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered '6 day tapering course, (6,5,4,3,2,1)'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4) - (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:31:12
User entered 'Oral (ORAL)'		09 Nov 2020 15:53:04

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered '18 Sep 2020'	(b) (4), (b) (6)	09 Nov 2020 15:53:04



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
DataPoint Verified.	(b) (4)	11 Nov 2020 02:31:12
User entered '23 Sep 2020'	(b) (4), (b) (6)	09 Nov 2020 15:53:04

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:00:33
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:29:28
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 21:29:18
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 21:29:18
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:18:54

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:31:12
User entered 'Yes (Y)'		09 Nov 2020 15:53:04

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User entered empty.	System	09 Nov 2020 15:53:04

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User entered empty.	System	09 Nov 2020 15:53:04

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:09
User entered empty.	System	09 Nov 2020 15:53:04



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Dec 2020 16:18:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 16:18:51
Data point term sent to Coder	System	01 Dec 2020 16:17:52
User entered 'Sulfamethoxazole'	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered 'urinary tract infection'	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160). Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:58:43
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160). Else, clarify.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	13 Apr 2021 21:11:32
User entered '800/160' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Apr 2021 21:11:28
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160). Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:06:36
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 15:49:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 15:49:57
User entered '800' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:49:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 16:17:34
User entered empty.	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 15:49:57
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:49:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 16:17:34
User entered empty.	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 15:49:57
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:49:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 16:17:34
User entered empty.	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34
	(b) (4)	

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:17:34



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 17:17:20
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:31:16
User entered '01 Oct 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	19 Mar 2021 21:31:09
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:32:36
User entered '24 Nov 2020'	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
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 as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 17:17:42
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 as appropriate.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:31:26
User entered 'No (N)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	19 Mar 2021 21:31:09
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 as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:24:28
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered '20 Oct 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	19 Mar 2021 21:31:09
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:17:34

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User entered 'l'	System	22 Jan 2021 15:49:57
User entered empty.	System	01 Dec 2020 16:17:34



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User entered 'l'	System	22 Jan 2021 15:49:57
User entered empty.	System	01 Dec 2020 16:17:34

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:15
User entered '804 (804)'	System	22 Jan 2021 15:49:57
User entered empty.	System	01 Dec 2020 16:17:34

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
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.	(b) (4) Coder Import (b) (4)	01 Dec 2020 16:20:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 16:20:33
Data point term sent to Coder	System	01 Dec 2020 16:18:55
User entered 'influenza vaccine'	Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'prophylaxis'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0.5'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered 'mL (mL)'	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'once (ONCE)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	01 Dec 2020 16:18:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User entered empty.	System	01 Dec 2020 16:18:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User entered empty.	System	01 Dec 2020 16:18:33

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:19
User entered empty.	System	01 Dec 2020 16:18:33

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #21 SULFAMETHOXAZOLE / (Start date 08 DEC 2020- Stop date 9 JAN 2021). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 09:19:21
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components and specify the # of tabs/capsules/ml's/puff for dose/units per eCRF completion guidelines for combination medications.' (Site from DM).		26 Mar 2021 09:16:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 15:19:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 15:19:42
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components and specify the # of tabs/capsules/ml's/puff for dose/units per eCRF completion guidelines for combination medications.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:18:50
Data point term sent to Coder	System	25 Mar 2021 15:18:38
Coding entries removed.	(b) (4), (b) (6)	25 Mar 2021 15:18:03
User entered 'SULFAMETHOXAZOLE / Trimethoprim' reason for change: New Information		25 Mar 2021 15:18:03

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #21 SULFAMETHOXAZOLE / (Start date 08 DEC 2020- Stop date 9 JAN 2021). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'duplicate entry deleted' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 18:59:31
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #21 SULFAMETHOXAZOLE / (Start date 08 DEC 2020- Stop date 9 JAN 2021). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).		17 Feb 2021 23:10:33
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components and specify the # of tabs/capsules/ml's/puff for dose/units per eCRF completion guidelines for combination medications. ' (Site from DM).		17 Feb 2021 23:10:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 15:53:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 15:53:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Jan 2021 15:52:39 22 Jan 2021 15:51:39
Coding entries removed.		22 Jan 2021 15:51:39
User entered 'SULFAMETHOXAZOLE' reason for change: New Information		22 Jan 2021 15:51:39

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 15:38:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 15:38:00
Data point term sent to Coder	System	22 Jan 2021 15:37:24
User entered 'Mirtazapine'	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 15:36:28



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Urinary Tract Infection' reason for change: New Information	(b) (4)	22 Jan 2021 15:51:39
User entered 'appetite booster'	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '400/80' reason for change: New Information	(b) (4)	
User entered '400' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:18:03
User entered '15'		22 Jan 2021 15:51:39
		22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '08 Dec 2020' reason for change: New Information	(b) (4)	22 Jan 2021 15:51:39
User entered '01 Oct 2020'	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)' reason for change: New Information	(b) (4)	22 Jan 2021 15:51:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:35:26
User entered '9 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	22 Jan 2021 15:51:39
User entered empty.		22 Jan 2021 15:36:28

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 15:36:28

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User entered 'I'	System	22 Jan 2021 15:36:28

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User entered 'I'	System	22 Jan 2021 15:36:28

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:22
User entered '804 (804)'	System	22 Jan 2021 15:36:28



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 06:50:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 06:50:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 17:06:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 17:06:07
Data point term sent to Coder	System	22 Jan 2021 15:53:39
User entered 'amoxicillin/clavulanate' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:53:20
Data point term sent to Coder	System	22 Jan 2021 15:38:26
User entered 'tamsulosin'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Urinary tract infection/Bladder Prostate health'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4) (h) (4)	23 Apr 2021 18:35:26
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) (6)	26 Mar 2021 09:16:26
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' (Site from DM).		25 Mar 2021 16:21:32
User entered '250/125' reason for change: Data Entry Error		25 Mar 2021 16:21:25
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).		17 Feb 2021 23:09:59
User entered '200/285' reason for change: Data Entry Error		22 Jan 2021 15:53:20
User entered '0.4'		22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'twice daily (BID)' reason for change:	(b) (4)	
New Information	(b) (4), (b) (6)	22 Jan 2021 15:53:20
User entered 'once daily (QD)'		22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:38:01



**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:35:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '11 Oct 2020' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 15:53:20
User entered '16 Oct 2020'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)' reason for change: New Information	(b) (4)	22 Jan 2021 15:53:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:53:20
User entered empty.		22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 15:53:20
User entered 'No (N)'		22 Jan 2021 15:43:38
		22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:35:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User entered '2'	System	22 Jan 2021 15:53:20
User entered '1'	System	22 Jan 2021 15:38:01



US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User entered 'I'	System	22 Jan 2021 15:38:01

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:28
User entered '804 (804)'	System	22 Jan 2021 15:38:01

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 11:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 11:45:53
Data point term sent to Coder	System	23 Apr 2021 07:58:49
Coding entries removed.	Dawn Killian (b) (4)	23 Apr 2021 07:58:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 08:23:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:23:01
Data point term sent to Coder	System	13 Apr 2021 21:05:29
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 21:04:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:43:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:43:58
Data point term sent to Coder	System	26 Feb 2021 20:34:37
User entered 'Tylenol codeine'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User closed query 'Per CDM: Response noted however, please consider to update 'indication' to include the 'location' of PAIN. Update as appropriate and ensure to add a medical condition and all applicable details to the AE eCRF.' (Site from DM). User signature succeeded.	(b) (4)	26 Apr 2021 13:04:42
	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
	(b) (4)	
Query 'Per CDM: Response noted however, please consider to update 'indication' to include the 'location' of PAIN. Update as appropriate and ensure to add a medical condition and all applicable details to the AE eCRF.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	23 Apr 2021 07:58:24
	(b) (4)	
User entered 'PAIN FROM CONCOMITANT PROCEDURE, Groin HERNIA REPAIR' reason for change: Data Entry Error	Dawn Killian (b) (4)	23 Apr 2021 07:58:18
	(b) (4)	
User opened query 'Per CDM: Response noted however, please consider to update 'indication' to include the 'location' of PAIN. Update as appropriate and ensure to add a medical condition and all applicable details to the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:06:55
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).		16 Apr 2021 10:06:55
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'Corrected source from "Administered for AE? Yes" to "Administered for AE? No"' (Site from DM).		13 Apr 2021 21:05:28
User entered 'PAIN FROM CONCOMITANT PROCEDURE, HERNIA REPAIR' reason for change: Data Entry Error		13 Apr 2021 21:04:54
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).		30 Mar 2021 16:08:18

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain from hernia repair'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:59:18
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	13 Apr 2021 21:14:16
User entered '30/300' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Apr 2021 21:13:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:01:29
User entered 'I'		26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	13 Apr 2021 21:13:39
User entered 'tablet (TABLET)'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 20:34:19



US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:34:19

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:34:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '2 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

US3292339

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

**US3292339**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 20:34:19



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User entered '4 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:34:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:35:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:38:58
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:33:54
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 21:33:46
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:01:37
User entered 'Yes (Y)'		26 Feb 2021 20:34:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User entered empty.	System	26 Feb 2021 20:34:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User entered empty.	System	26 Feb 2021 20:34:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:35:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:22:36
User entered empty.	System	26 Feb 2021 20:34:19

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:35:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:36
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:12:55
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	03 Nov 2020 19:38:04

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:35:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:22:34

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered 'Neck/Maxillofacial CT'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:22:34



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:22:34

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:35:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 20:22:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:35:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered '17 Sep 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:23:36

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:35:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered 'Chest X-ray'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:23:36

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 20:23:36

US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:35:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:13:24
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 20:23:36

US3292339

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 16:35:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:10:07

US3292339

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'hernia repair'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:10:07



US3292339

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:35:15

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please verify the Indication as there no corresponding Medical History that match this Procedure/Surgery. Please review and update accordingly, else provide MH logline number.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:20:38
Query 'Per CDM: Please verify the Indication as there no corresponding Medical History that match this Procedure/Surgery. Please review and update accordingly, else provide MH logline number.' answered with 'added groin hernia ' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 21:23:20
User opened query 'Per CDM: Please verify the Indication as there no corresponding Medical History that match this Procedure/Surgery. Please review and update accordingly, else provide MH logline number.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 14:10:05
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered 'Medical History (MH)'	(b) (4), (b) (6)	26 Feb 2021 21:10:07

US3292339

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 16:35:15**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:10:07

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.		01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45



**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:35:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:35:56
User entered '20/Sep/2020 14:14'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:35:15

**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.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	02 Oct 2020 20:35:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'l'		20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:35:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
User entered '01/Oct/2020 12:46'	System	01 Oct 2020 12:46:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:35:15

**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.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:49:23
User entered 'l'		01 Oct 2020 12:46:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.		01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:35:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
User entered '20/Oct/2020 19:49'	System	20 Oct 2020 19:49:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:35:15

**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.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:50:07
User entered 'l'		20 Oct 2020 19:49:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.		01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13



**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13



**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:35:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
User entered '04/Nov/2020 10:30'	System	04 Nov 2020 15:30:48

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:35:15

**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.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
Reviewed for Safety.	(b) (4)	18 Feb 2021 21:15:04
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:56
User entered 'l'		04 Nov 2020 15:30:48

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:35:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '18/Feb/2021 16:15'	(b) (4) System	18 Feb 2021 21:15:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:35:15

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 21:15:34

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'USA-US072-2020-MRNA-1273-P301000002'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
Un-reviewed for Safety.	System	30 Sep 2020 22:29:31
User entered 'Yes (Y)'	System	30 Sep 2020 22:29:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Yes (Y)'	System	20 Sep 2020 18:14:13

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:35:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'No (N)'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Douglas'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'Denham'	System	20 Sep 2020 18:14:13



US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '7940 Floyd Curl Drive'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered 'San Antonio'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:14:39
User entered '78229'	System	20 Sep 2020 18:14:13

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
DataPoint Verified.	(b) (4)	05 Nov 2020 16:05:56
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:46:20
User entered 'US'	System	20 Sep 2020 18:14:45

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:35:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '6'	(b) (4)	19 Feb 2021 15:02:51
User entered '5'	System	18 Feb 2021 21:15:34
User entered '4'	System	04 Nov 2020 15:30:48
User entered '3'	System	20 Oct 2020 19:49:34
User entered '2'	System	01 Oct 2020 12:46:34
User entered '1'	System	20 Sep 2020 18:14:45

**US3292339**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:35:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered '19/Feb/2021 10:02'	(b) (4) System	19 Feb 2021 15:02:51

US3292339

Folder: SAE USA-US072-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:35:15

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:15
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:20:00
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 15:02:51