

US3362069 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:13:22

All time stamps listed in this document are displayed in GMT

US3362069

**Form: Participant Creation**

**Data signed:** (b) (4) 24 Apr 2021 00:05:04

**Generated On: 09 Jun 2021 17:13:22**

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[Participant ID](#)

US3362069

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

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US3362069

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 07 AUG 2020

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

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Folder OID SCRN

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US3362069

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
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

US3362069

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Date of Informed Consent (*dd MMM yyyy*) 07 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version  
Amendment 1   
Amendment 2   
Amendment 3   
Amendment 4   
Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail  
Withdrew Consent   
Inclusion/Exclusion   
Cohort Full   
Other

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

Was this participant screened previously? Yes   
No

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

Enrollment Trigger 1

US3362069

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

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Did the participant meet all eligibility criteria?

Yes

No

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US3362069

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

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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) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	HYPERTENSION
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)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	HYPERLIPIDEMIA
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)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362069

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362069

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362069

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	PERICARDECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	RIGHT CHEEK EXCISION OF MELANOMA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	BASAL CELL OF THE SCALP
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 (10)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	GOUT- MULTIPLE LOCATIONS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	PERICARDITIS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3362069

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3362069

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:14:39

Generated On: 09 Jun 2021 17:13:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	07:55 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 07:55
Height ( <i>xxx.x</i> )	181 cm
Weight ( <i>xxx.x</i> )	96 kg
BMI ( <i>xxx.x</i> )	29.30313 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3362069

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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US3362069

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

---

**Specify** \_\_\_\_\_

---

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

**No Risk Identified** False

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

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US3362069

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:14:38

Generated On: 09 Jun 2021 17:13:22

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	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>	

US3362069

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 07 AUG 2020

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

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Folder OID VISIT1

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US3362069

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143267

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

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Height	ND - Not Done
Weight	ND - Not Done

---

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	07:55 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 07:55
Temperature ( <i>xxx.x</i> )	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	89 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:46 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:46
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	89 mmHg
Diastolic Blood Pressure units	MMHG

US3362069

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

07 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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US3362069

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 07 AUG 2020

What was the treatment time? (00:00-23:59) 09:01 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 09:01

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) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	07 AUG 2020
Collection time ( <i>00:00-23:59</i> )	08:28 (24 HR)
Collection date and time (derived)	07 AUG 2020 08:28

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US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

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Collection date ( <i>dd MMM yyyy</i> )			07 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	07 AUG 2020 08:15
Nasopharyngeal Swab 2	No		

---



US3362069

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 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 07 AUG 2020 09:35

PC Open Date & Time 07 AUG 2020 09:21

PC Close Date & Time 07 AUG 2020 11:51

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 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 07 AUG 2020 19:23  
PC Open Date & Time 07 AUG 2020 12:46  
PC Close Date & Time 08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 19:33
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 20:45
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 20:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 19:44
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 19:50
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 19:53
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**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

07 AUG 2020 09:36

PC Open Date & Time

07 AUG 2020 09:21

PC Close Date & Time

07 AUG 2020 11:51

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	07 AUG 2020 19:28
PC Open Date & Time	07 AUG 2020 12:46
PC Close Date & Time	08 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	08 AUG 2020 19:34
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 20:45

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 20:02

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 AUG 2020 19:45
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

12 AUG 2020 19:51

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	13 AUG 2020 19:54
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

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

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

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

No   
Yes

PC Time stamp	07 AUG 2020 09:38
PC Open Date & Time	07 AUG 2020 09:21
PC Close Date & Time	07 AUG 2020 11:51

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

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

No

Yes

PC Time stamp	07 AUG 2020 19:29
PC Open Date & Time	07 AUG 2020 12:46
PC Close Date & Time	08 AUG 2020 11:59

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

**HEADACHE**

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

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	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 19:35
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

**HEADACHE**

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

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	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 20:46
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

**HEADACHE**

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

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Yes

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PC Time stamp	10 AUG 2020 20:03
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

**HEADACHE**

None

No interference with activity

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

Any use of prescription pain  
reliever or prevents daily activity

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily  
activity

**MUSCLE ACHES ALL OVER BODY**

None

No interference with activity

Some interference with activity

Significant; prevents daily  
activity

**JOINT ACHES IN SEVERAL JOINTS**

None

No interference with activity

Some interference with activity

Significant; prevents daily  
activity

**NAUSEA/VOMITING**

None

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

Some interference with activity  
or >2 episodes/24 hours

Prevents daily activity, requires  
outpatient IV hydration

**CHILLS**

None

No interference with activity

Some interference with activity  
not requiring medical attention

Prevents daily activity and  
requires medical attention

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

No

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

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Yes

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PC Time stamp	11 AUG 2020 19:45
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 19:52
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

---

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

---

Yes

---

PC Time stamp	13 AUG 2020 19:55
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

---

US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 19:34
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3362069

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 AUG 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3362069

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3362069

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

---

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	07:37 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 07:37
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	78 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:08 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 09:08
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG

US3362069

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

4 SEP 2020

---

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

---

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 04 SEP 2020

What was the treatment time? (00:00-23:59) 08:26 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 08:26

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

US3362069

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 4 SEP 2020

---

Collection time (*00:00-23:59*) 07:48 (24 HR)

---

Collection date and time (derived) 4 SEP 2020 07:48

---

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Collection date ( <i>dd MMM yyyy</i> )			4 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:47	4 SEP 2020 07:47
Nasopharyngeal Swab 2	No		

---

US3362069

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 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 04 SEP 2020 08:58

PC Open Date & Time 04 SEP 2020 08:46

PC Close Date & Time 04 SEP 2020 11:16

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 99.0 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 21:25

PC Open Date & Time 04 SEP 2020 12:11

PC Close Date & Time 05 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 05 SEP 2020 19:25

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 16:56
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 20:54
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

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

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

PC Time Stamp	09 SEP 2020 04:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 20:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 20:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**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	04 SEP 2020 08:59
PC Open Date & Time	04 SEP 2020 08:46
PC Close Date & Time	04 SEP 2020 11:16

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

95

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

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

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

04 SEP 2020 21:29

PC Open Date & Time

04 SEP 2020 12:11

PC Close Date & Time

05 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

05 SEP 2020 19:27

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	06 SEP 2020 16:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 20:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 04:59

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 20:13

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 SEP 2020 20:32
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

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

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

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

No

Yes

---

PC Time stamp	04 SEP 2020 09:00
PC Open Date & Time	04 SEP 2020 08:46
PC Close Date & Time	04 SEP 2020 11:16

---

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

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

No

Yes

PC Time stamp	04 SEP 2020 21:31
PC Open Date & Time	04 SEP 2020 12:11
PC Close Date & Time	05 SEP 2020 11:59

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 2

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 19:30
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

---

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 3

**HEADACHE**

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 16:58
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

---



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 4

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 20:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

---

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 5

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 04:59
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

---

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 6

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 20:14
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

---

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 7

**HEADACHE**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

**FATIGUE**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**MUSCLE ACHES ALL OVER BODY**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**JOINT ACHES IN SEVERAL JOINTS**

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

**NAUSEA/VOMITING**

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

**CHILLS**

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

---

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 20:32
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

---



US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None

**HEADACHE**

No interference with activity

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

Any use of prescription pain  
reliever or prevents daily activity

---

PC Time Stamp 12 SEP 2020 07:21

---

PC Open Date & Time 11 SEP 2020 12:00

---

PC Close Date & Time 12 SEP 2020 11:59

---

US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 07:21
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3362069

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:08

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3362069

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 2 OCT 2020

---

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

---

Folder OID VISIT3

---

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 02 OCT 2020

Time of assessment (*00:00-23:59*) 08:20 (24 HR)

Vital Signs Date and Time (derived) 02 OCT 2020 08:20

Temperature (*xxx.x*) 36.8 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (*xxx*) 71 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 18 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 135 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 72 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3362069

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 OCT 2020

---

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

---

US3362069

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	2 OCT 2020
Collection time ( <i>00:00-23:59</i> )	08:27 (24 HR)
Collection date and time (derived)	2 OCT 2020 08:27

---

US3362069

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:09

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	07 OCT 2020 04:51:26
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

---

<b>TIMEPOINT</b>	<b>DAY 71</b>
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 12:00:52
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

---

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 10:46:21
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 99

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

No

Yes

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

No

Yes

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

Date and time of submission 11 NOV 2020 14:28:21

Patient Cloud Open Date & Time 11 NOV 2020 00:01

Patient Cloud Close Date & Time 15 NOV 2020 23:59

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 106

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

No

Yes

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

No

Yes

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

Date and time of submission 18 NOV 2020 12:48:34

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 20:18:57
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 NOV 2020 19:13:09
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 124

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

No

Yes

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

No

Yes

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

Date and time of submission 06 DEC 2020 06:44:05

Patient Cloud Open Date & Time 06 DEC 2020 00:01

Patient Cloud Close Date & Time 10 DEC 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	13 DEC 2020 06:45:44
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	20 DEC 2020 06:52:15
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 11:38:41
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 05 JAN 2021 21:04:14

Patient Cloud Open Date & Time 03 JAN 2021 00:01

Patient Cloud Close Date & Time 07 JAN 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 10 JAN 2021 07:43:23

Patient Cloud Open Date & Time 10 JAN 2021 00:01

Patient Cloud Close Date & Time 14 JAN 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 06:14:59
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 06:31:11
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 FEB 2021 15:13:46
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 187

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

No

Yes

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

No

Yes

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

Date and time of submission 07 FEB 2021 09:26:46

Patient Cloud Open Date & Time 07 FEB 2021 00:01

Patient Cloud Close Date & Time 11 FEB 2021 23:59



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 FEB 2021 09:26:11
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 08:06:20
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 28 FEB 2021 13:12:41

Patient Cloud Open Date & Time 28 FEB 2021 00:01

Patient Cloud Close Date & Time 04 MAR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 215

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

No

Yes

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

No

Yes

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

Date and time of submission 09 MAR 2021 18:01:04

Patient Cloud Open Date & Time 07 MAR 2021 00:01

Patient Cloud Close Date & Time 11 MAR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission

17 MAR 2021 23:17:29

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 10:55:47
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 10:30:59
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	04 APR 2021 12:14:32
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 APR 2021 10:01:24
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 06:30:49
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 APR 2021 04:04:51
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAY 2021 06:53:10
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 299

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUN 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 313

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 320

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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24 JUN 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 327

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 334

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 341

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 348

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 AUG 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 369

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3362069

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**TIMEPOINT**

DAY 376

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

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US3362069

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 390

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 397

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 404

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 411

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

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

US3362069

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 425

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 446

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 460

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 474

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 481

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 488

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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

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[Patient Cloud Close Date & Time](#) 09 DEC 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 495

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

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

US3362069

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 509

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 516

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

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

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

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

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JAN 2022 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 523

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 530

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 537

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JAN 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#) 03 FEB 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 551

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 10 FEB 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 558

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3362069

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 565

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 572

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 MAR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 579

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 MAR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 600

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

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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 607

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 614

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 621

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 628

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 642

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 649

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAY 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JUN 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 670

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

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

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 677

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59



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**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

US3362069

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUN 2022 23:59

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US3362069

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 691

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

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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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Date and time of submission

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26 JUN 2022 00:01

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30 JUN 2022 23:59

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US3362069

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Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3362069**

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**Generated On: 09 Jun 2021 17:13:22**

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 705

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

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

**US3362069**

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

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**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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**Generated On: 09 Jun 2021 17:13:22**

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Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 719

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3362069

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

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**Generated On: 09 Jun 2021 17:13:22**

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 726

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 733

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 740

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

---

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 761

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 768

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

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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#) 15 SEP 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 782

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3362069**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 789

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°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

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 06 OCT 2022 23:59

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US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

---

US3362069

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:13:22

---

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:12:15

---

US3362069

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:17:28

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 OCT 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3362069

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:17:27

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 DEC 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

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*

---

---



US3362069

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 JAN 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 FEB 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID VISIT4

---

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3362069

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy) \_\_\_\_\_

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3362069

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	19 FEB 2021
Collection time ( <i>00:00-23:59</i> )	07:48 (24 HR)
Collection date and time (derived)	19 FEB 2021 07:48

---

US3362069

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3362069

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 APR 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3362069

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:06

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3362069

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) \_\_\_\_\_

Please select one status for the follow-up contact Contact Made   
Contact Not Made

Comments \_\_\_\_\_

*If Contact Not Made, please provide Comments* \_\_\_\_\_

US3362069

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3362069

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:22

---

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"/>

---

US3362069

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:13:22

---

Generate Next COVID-19 Assessment

Yes

No

---

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 JAN 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID UNBLND\_DECIDE

---

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

Date of updated informed consent (*dd MMM yyyy*) 29 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes   
No

Under what version of the Protocol was the Participant unblinded? Amendment 5   
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 29 JAN 2021

Participant randomization assignment mRNA-1273   
Placebo

Actual Dose 1 mRNA-1273   
Placebo   
Not Administered

Actual Dose 2 mRNA-1273   
Placebo   
Not Administered

Will participant receive mRNA-1273? Yes   
No

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 JAN 2021

---

Collection time (*00:00-23:59*) 07:22 (24 HR)

---

Collection date and time (derived) 29 JAN 2021 07:22

---

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	29 JAN 2021
Collection time ( <i>00:00 - 23:59</i> )	07:24
Collection Date and Time (derived)	29 JAN 2021 07:24

---

US3362069

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:10:49

Generated On: 09 Jun 2021 17:13:22

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

AEID USA-US112-2020-MRNA-1273-P30  
1000014

Adverse event PARTIAL BOWEL  
OBSTRUCTION -ILEUM

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) 6 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 11 DEC 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 True

Hospital Admission Date (dd MMM yyyy) 6 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 11 DEC 2020

Admitted to ICU? Yes   
No   
Unknown

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US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

---

Number of Days in ICU \_\_\_\_\_

---

Persistent or significant disability or incapacity False

---

Congenital anomaly or birth defect False

---

Other medically important event False

---

Relationship to investigational product Not Related   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None True

---

Concomitant Medication False

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

---

Narrative \_\_\_\_\_

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

---

SUBJECT CONTACTED SITE TO NOTIFY OF HOSPITALIZATION ON 06DEC2020 FOR PARTIAL BOWEL OBSTRUCTION OF ILEUM;. WILL SIGN MEDICAL RELEASE TO UPDATE CHART. NO SURGICAL OR MEDICINAL INTERVENTION REQUIRED. AE RESOLVED WITH BOWEL REST.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

AEID	
Adverse event	DRY EYES
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)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

AEID	
Adverse event	POOR DENTITION
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)	22 JAN 2021
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)	26 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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) 09 Apr 2021 00:42:40

Generated On: 09 Jun 2021 17:13:22

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related   
Related   
Not Applicable

Relationship to Study Procedure Not Related   
Related   
Not Applicable

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

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)

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

---

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication SIMVASTATIN

Prophylaxis Yes   
No

Indication HYPERLIPIDEMIA

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 (1)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication CASCARA SAGRADA

Prophylaxis Yes   
No

Indication CONSTIPATION

Dose per administration 450

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) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2014

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication TESTOSTERONE

Prophylaxis Yes   
No

Indication HYPOGONADISM

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 (4)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2017

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication ALLOPURINOL

Prophylaxis Yes   
No

Indication GENERAL GOUT

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication ADVIL

Prophylaxis Yes   
No

Indication REACTION (E-DIARY DAY 1  
AND 2) TO TREAT PAIN/FEVER

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) 04 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 04 SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication ADVIL

Prophylaxis Yes   
No

Indication LOWER BACK PAIN

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2017

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication AMBIAN

Prophylaxis Yes   
No

Indication INSOMNIA

Dose per administration 12.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2014

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 26 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication AMOXICILLIN

Prophylaxis Yes   
No

Indication TOOTH IMPLANT

Dose per administration 500

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 21 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 26 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication LUNESTA

Prophylaxis Yes   
No

Indication INSOMNIA

Dose per administration 3

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 26 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Name of Medication XIIDRA

Prophylaxis Yes   
No

Indication DRY EYES

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify DROP

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

	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 checked="" type="radio"/>

---

If route of administration is Other, specify	OPHTHALMIC
Start date ( <i>dd MMM yyyy</i> )	26 MAR 2021
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

---

If not Ongoing, End date ( <i>dd MMM yyyy</i> )	
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"/>

---

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:48:26

Generated On: 09 Jun 2021 17:13:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 DEC 2020	MOHS SURGERY FOR BASAL CELL CARCINOMA	Medical History	
22 JAN 2021	DENTAL IMPLANT	Adverse Event	

US3362069

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:13:22

---

Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by  
participant (specify)

Due to SARS-COV-2

Other

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

---

US3362069

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:13:22

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

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P30 1000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/DEC/2020 13:22
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	True

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/DEC/2020 14:51
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	True



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/DEC/2020 09:14
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/DEC/2020 11:35
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/JAN/2021 20:35
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/JAN/2021 11:24
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Data signed: (b) (4) 24 Apr 2021 00:05:04

Generated On: 09 Jun 2021 17:13:22

SAEID	USA-US112-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/JAN/2021 14:55
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	True

Audit

US3362069 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362069

Form: Participant Creation

Generated On: 09 Jun 2021 17:13:22

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'US3362069'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:45

US3362069

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 14:02:59



US3362069

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:46

US3362069

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	07 Aug 2020 14:02:59

US3362069

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'SCRN'	System	07 Aug 2020 14:02:59

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:47

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '63'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'YEARS'	System	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '63'	System	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15



US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15



US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:22

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:15

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '07 Aug 2020'	Crystal Rowell (b) (4)	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Aug 2020'	System	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2020'	System	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Amendment 1 (1)'	Crystal Rowell (b) (4)	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	10 Apr 2021 00:14:39
User closed query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	System	10 Aug 2020 14:49:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 14:49:57
User opened query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	System	10 Aug 2020 14:49:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 14:49:43
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User closed query 'Was participant enrolled in the study is No, however reason for screen fail is missing. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 14:49:57
User opened query 'Was participant enrolled in the study is No, however reason for screen fail is missing. Please provide.' (Site from System).	System	10 Aug 2020 14:49:43
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 14:03:25
	(b) (4)	



US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) Crystal Rowell (b) (4)	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:49:57
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	07 Aug 2020 14:03:25

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	10 Aug 2020 14:49:57
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	07 Aug 2020 14:03:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:39:46

US3362069

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '1'	System	10 Aug 2020 14:49:57
User entered empty.	System	10 Aug 2020 14:49:43
User entered '1'	System	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:13:22

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:13:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:29:37

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:53:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:53:11
Data point term sent to Coder	System	10 Aug 2020 14:50:45
User entered 'hypertension'	(b) (4), (b) (6)	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:25



US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2015'	System	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2015'	System	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:50:25

US3362069

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:50:25



US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Metabolism and nutrition disorders, HLG T: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:20
Data point term sent to Coder	System	10 Aug 2020 14:51:46
User entered 'hyperlipidemia'	(b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2015'	System	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2015'	System	10 Aug 2020 14:50:50



US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:50:50

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Endocrine disorders, HLG: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
Data point term sent to Coder	System	10 Aug 2020 14:51:46
User entered 'hypogonadism'	(b) (4), (b) (6)	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:05



US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2017'	System	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2017'	System	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:05

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
Data point term sent to Coder	System	10 Aug 2020 14:51:47
User entered 'insomnia'	(b) (4), (b) (6)	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:22



US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:22

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:54:19
Data point term sent to Coder	System	10 Aug 2020 14:51:47
User entered 'constipation'	(b) (4), (b) (6)	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:36



US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:36

US3362069

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	10 Aug 2020 14:51:36



US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:56:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:56:24
Data point term sent to Coder	System	10 Aug 2020 14:52:48
User entered 'appendectomy'	(b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2018'	System	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2018'	System	10 Aug 2020 14:52:06



US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2018'	System	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2018'	System	10 Aug 2020 14:52:06

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:49:39
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'percarditis will update' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:15:32
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:24:46
User coded data point as SOC: Surgical and medical procedures, HLG: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Pericardial excision, LLT: Pericardiectomy - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 11:28:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 11:28:21
Data point term sent to Coder	System	10 Aug 2020 14:53:51
User entered 'pericardiectomy'	(b) (4), (b) (6)	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:52:54



US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	10 Aug 2020 14:52:54

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Malignant melanoma excision - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:49:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:49:57
Data point term sent to Coder	System	10 Aug 2020 14:53:51
User entered 'right cheek excision of melanoma'	(b) (4), (b) (6)	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:53:25



US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2018'	System	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2018'	System	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2018'	System	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2018'	System	10 Aug 2020 14:53:25

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 06:42:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 06:42:24
Data point term sent to Coder	System	10 Aug 2020 14:54:53
User entered 'basal cell of the scalp'	(b) (4), (b) (6)	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:01



US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2000'	System	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2000'	System	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2000'	System	10 Aug 2020 14:54:01

US3362069

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2000'	System	10 Aug 2020 14:54:01



US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 20:39:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 20:39:46
Data point term sent to Coder	System	18 Sep 2020 21:08:03
Coding entries removed.	Crystal Rowell (b) (4)	18 Sep 2020 21:07:39
User entered 'GOUT- multiple locations' reason for change: Data Entry Error	Crystal Rowell (b) (4)	18 Sep 2020 21:07:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 15:43:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 15:43:21
Data point term sent to Coder	System	19 Aug 2020 15:42:24
User entered 'Gout'	(b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2010'	System	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2010'	System	19 Aug 2020 15:41:32



US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	19 Aug 2020 15:41:32

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Cardiac disorders, HLGHT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 15:17:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 15:17:47
Data point term sent to Coder	System	25 Sep 2020 15:16:40
User entered 'Pericarditis'	(b) (4), (b) (6)	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:16:28



US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2014'	System	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2014'	System	25 Sep 2020 15:16:28

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\23.0.	Coder Import (b) (4)	25 Sep 2020 15:18:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Sep 2020 15:18:50
Data point term sent to Coder	System	25 Sep 2020 15:17:41
User entered 'Lower back pain'	(b) (4), (b) (6)	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:17:06



US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'Jan 2017'	System	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '2017'	System	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered empty.	System	25 Sep 2020 15:17:06

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:32:32



US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User closed query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' (Site from DM).	(b) (4)	25 Sep 2020 08:34:52
Query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' answered with 'per 24 hour time clock, 0755 is AM' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:22:33
User opened query 'Per CDM: Please confirm if time 07:55 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:33:19
User entered '07:55'	(b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered '07 Aug 2020 07:55'	System	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
DataPoint set to visible.	(b) (4)	10 Aug 2020 14:49:57
DataPoint set to invisible.	System	10 Aug 2020 14:49:43
User entered '181' cm	(b) (4), (b) (6)	10 Aug 2020 14:32:32
DataPoint set to visible.	System	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
DataPoint set to visible.	(b) (4)	10 Aug 2020 14:49:57
DataPoint set to invisible.	System	10 Aug 2020 14:49:43
User entered '96' kg	(b) (4), (b) (6)	10 Aug 2020 14:32:32
DataPoint set to visible.	System	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
Amendment Manager: User entered '29.30313'	System	16 Sep 2020 23:46:56
DataPoint set to visible.	System	10 Aug 2020 14:49:57
DataPoint set to invisible.	System	10 Aug 2020 14:49:43
User entered '29.3'	System	10 Aug 2020 14:32:32
DataPoint set to visible.	System	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
DataPoint set to visible.	System	10 Aug 2020 14:49:57
DataPoint set to invisible.	System	10 Aug 2020 14:49:43
User entered 'kg/m2'	System	10 Aug 2020 14:32:32
DataPoint set to visible.	System	07 Aug 2020 14:03:33

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 07:45:10
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'Data updated per query resolution.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:46:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:45:05
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:56:05
User entered '37' C	(b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:45:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Aug 2020 14:32:32



US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	22 Sep 2020 14:45:05
User entered '84'	(b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'bpm'	System	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:45:05
User entered '16'	(b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'breaths/min'	System	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:45:05
User entered '152'	(b) (4), (b) (6)	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'mmHg'	System	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:45:05
User entered '84'	(b) (4), (b) (6)	10 Aug 2020 14:32:32



US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User entered 'mmHg'	System	10 Aug 2020 14:32:32

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21

US3362069

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21

US3362069

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:04

US3362069

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:26:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 14:05:02
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 14:33:04

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

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[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43



US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:21
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:39
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:43

US3362069

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:57

US3362069

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:57

US3362069

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:33:57

US3362069

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'VISIT1'	System	10 Aug 2020 14:33:57

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:40:00

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:47:26
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 13:40:00
User entered '143267' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:40:00



US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 13:40:00

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:40:57

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:40:57

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:40:57

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:40:57

US3362069

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:22

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:40:57

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 05:25:13
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:49:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 12:49:31
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:45:04
User entered '181' cm	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	23 Sep 2020 12:49:31
User entered '96' kg	(b) (4), (b) (6)	10 Aug 2020 14:47:29



US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 05:25:13
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:49:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 12:49:31
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:45:04
User entered '181' cm	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	23 Sep 2020 12:49:31
User entered '96' kg	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07:55'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '07 Aug 2020 07:55'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '37' C	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29



US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '89'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'bpm'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'breaths/min'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '152'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	10 Aug 2020 14:47:29



US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '84'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 05:25:13
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:49:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 12:49:31
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:45:04
User entered '181' cm	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:22

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	23 Sep 2020 12:49:31
User entered '96' kg	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:36:37
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 14:47:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 14:47:29
User entered '09:46'	(b) (4), (b) (6)	10 Aug 2020 14:47:29



US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '07 Aug 2020 09:46'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '66'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'bpm'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '18'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'breaths/min'	System	10 Aug 2020 14:47:29



US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '140'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	10 Aug 2020 14:47:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '89'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	10 Aug 2020 14:47:29

US3362069

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:49

US3362069

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:47:49

US3362069

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 14:05:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 14:05:31



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) Crystal Rowell (b) (4)	07 Aug 2020 14:05:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 14:05:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	Crystal Rowell (b) (4)	07 Aug 2020 14:05:31

US3362069

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '09:01'	Crystal Rowell (b) (4)	07 Aug 2020 14:05:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '07 Aug 2020 09:01'	System	07 Aug 2020 14:05:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Left Arm (LEFT ARM)'	Crystal Rowell (b) (4)	07 Aug 2020 14:05:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'ONCE'	System	07 Aug 2020 14:05:31

US3362069

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 14:05:31



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:18

US3362069

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:18

US3362069

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '08:28'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:18

US3362069

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '07 Aug 2020 08:28'	System	10 Aug 2020 14:48:18

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '08:15'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:39



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '07 Aug 2020 08:15'	System	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered empty.	System	10 Aug 2020 14:48:39

US3362069

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:48:44

US3362069

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	10 Aug 2020 14:48:44

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:23:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fcee891-a047-4f65-b634-891df2aa3b7a' User entered 'Yes (Y)'	System	07 Aug 2020 14:35:56
	System	07 Aug 2020 14:35:56

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:35:32', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fcee891-a047-4f65-b634-891df2aa3b7a' User entered '98.4'	System	07 Aug 2020 14:35:56
	System	07 Aug 2020 14:35:56

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:35:38', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fcee891-a047-4f65-b634-891df2aa3b7a'	System	07 Aug 2020 14:35:56
User entered 'No (N)'	System	07 Aug 2020 14:35:56

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:35:54', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fcee891-a047-4f65-b634-891df2aa3b7a' User entered '07 Aug 2020 09:35'	System	07 Aug 2020 14:35:56
	System	07 Aug 2020 14:35:56

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 09:21'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 11:51'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:23:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9f140fe4-12a5-49ac-b128-e6d053b5dfab' User entered 'Yes (Y)'	System	08 Aug 2020 00:23:58
	System	08 Aug 2020 00:23:58



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:23:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9f140fe4-12a5-49ac-b128-e6d053b5dfab' User entered '98.4'	System	08 Aug 2020 00:23:58
	System	08 Aug 2020 00:23:58

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:23:41', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9f140fe4-12a5-49ac-b128-e6d053b5dfab' User entered 'No (N)'	System	08 Aug 2020 00:23:58
	System	08 Aug 2020 00:23:58

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:23:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9f140fe4-12a5-49ac-b128-e6d053b5dfab' User entered '07 Aug 2020 19:23'	System	08 Aug 2020 00:23:58
	System	08 Aug 2020 00:23:58

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 12:46'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 2'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:32:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fa80abe-63b6-42af-9281-74bc5bcd002'	System	09 Aug 2020 00:33:46
User entered 'Yes (Y)'	System	09 Aug 2020 00:33:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:32:55', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fa80abe-63b6-42af-9281-74bc5bced002' User entered '98.8'	System	09 Aug 2020 00:33:46
	System	09 Aug 2020 00:33:46



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:33:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fa80abe-63b6-42af-9281-74bc5bcd002'	System	09 Aug 2020 00:33:46
User entered 'No (N)'	System	09 Aug 2020 00:33:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:33:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8fa80abe-63b6-42af-9281-74bc5bcd002' User entered '08 Aug 2020 19:33'	System	09 Aug 2020 00:33:46
	System	09 Aug 2020 00:33:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 3'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:44:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e4c1e27d-7839-460b-bdb4-c99b3af05be9' User entered 'Yes (Y)'	System	10 Aug 2020 01:45:04
	System	10 Aug 2020 01:45:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:44:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e4c1e27d-7839-460b-bdb4-c99b3af05be9' User entered '98.3'	System	10 Aug 2020 01:45:04
	System	10 Aug 2020 01:45:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:44:50', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e4c1e27d-7839-460b-bdb4-c99b3af05be9' User entered 'No (N)'	System	10 Aug 2020 01:45:04
	System	10 Aug 2020 01:45:04



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:03', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e4c1e27d-7839-460b-bdb4-c99b3af05be9' User entered '09 Aug 2020 20:45'	System	10 Aug 2020 01:45:04
	System	10 Aug 2020 01:45:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 4'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:01:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4d7aeb76-1624-4a23-8187-5b9632a73f40' User entered 'Yes (Y)'	System	11 Aug 2020 01:02:04
	System	11 Aug 2020 01:02:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:01:41', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4d7aeb76-1624-4a23-8187-5b9632a73f40' User entered '98.6'	System	11 Aug 2020 01:02:04
	System	11 Aug 2020 01:02:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:01:47', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4d7aeb76-1624-4a23-8187-5b9632a73f40' User entered 'No (N)'	System	11 Aug 2020 01:02:04
	System	11 Aug 2020 01:02:04

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4d7aeb76-1624-4a23-8187-5b9632a73f40'	System	11 Aug 2020 01:02:04
User entered '10 Aug 2020 20:02'	System	11 Aug 2020 01:02:04



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 5'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4f778e34-707f-4418-9ba2-bcaa95d9089c' User entered 'Yes (Y)'	System	12 Aug 2020 00:44:41
	System	12 Aug 2020 00:44:41

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:18', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4f778e34-707f-4418-9ba2-bcaa95d9089c' User entered '98.5'	System	12 Aug 2020 00:44:41
	System	12 Aug 2020 00:44:41

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4f778e34-707f-4418-9ba2-bcaa95d9089c' User entered 'No (N)'	System	12 Aug 2020 00:44:41
	System	12 Aug 2020 00:44:41

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4f778e34-707f-4418-9ba2-bcaa95d9089c' User entered '11 Aug 2020 19:44'	System	12 Aug 2020 00:44:41
	System	12 Aug 2020 00:44:41

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 6'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:49:55', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0f3e2ad0-ce37-4036-bbf7-6f9069d702d4' User entered 'Yes (Y)'	System	13 Aug 2020 00:50:46
	System	13 Aug 2020 00:50:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:50:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0f3e2ad0-ce37-4036-bbf7-6f9069d702d4' User entered '98.3'	System	13 Aug 2020 00:50:46
	System	13 Aug 2020 00:50:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:50:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0f3e2ad0-ce37-4036-bbf7-6f9069d702d4'	System	13 Aug 2020 00:50:46
User entered 'No (N)'	System	13 Aug 2020 00:50:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:50:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0f3e2ad0-ce37-4036-bbf7-6f9069d702d4' User entered '12 Aug 2020 19:50'	System	13 Aug 2020 00:50:46
	System	13 Aug 2020 00:50:46

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 7'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b7fa4af-9f2b-4ec1-8f04-c1107caea1ec' User entered 'Yes (Y)'	System	14 Aug 2020 00:53:26
	System	14 Aug 2020 00:53:26

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b7fa4af-9f2b-4ec1-8f04-c1107caea1ec' User entered '98.5'	System	14 Aug 2020 00:53:26
	System	14 Aug 2020 00:53:26

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:16', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b7fa4af-9f2b-4ec1-8f04-c1107caea1ec' User entered 'No (N)'	System	14 Aug 2020 00:53:26
	System	14 Aug 2020 00:53:26

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b7fa4af-9f2b-4ec1-8f04-c1107caea1ec' User entered '13 Aug 2020 19:53'	System	14 Aug 2020 00:53:26
	System	14 Aug 2020 00:53:26

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:36:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04e3dc6b-d68e-4e43-9c9d-81cf3309ef9e'	System	07 Aug 2020 14:36:47
User entered 'None (1)'	System	07 Aug 2020 14:36:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:36:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04e3dc6b-d68e-4e43-9c9d-81cf3309ef9e' User entered 'No (N)'	System	07 Aug 2020 14:36:47
	System	07 Aug 2020 14:36:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:36:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04e3dc6b-d68e-4e43-9c9d-81cf3309ef9e'	System	07 Aug 2020 14:36:47
User entered 'No (N)'	System	07 Aug 2020 14:36:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:36:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04e3dc6b-d68e-4e43-9c9d-81cf3309ef9e'	System	07 Aug 2020 14:36:47
User entered 'None (1)'	System	07 Aug 2020 14:36:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:36:43', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04e3dc6b-d68e-4e43-9c9d-81cf3309ef9e' User entered '07 Aug 2020 09:36'	System	07 Aug 2020 14:36:47
	System	07 Aug 2020 14:36:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 09:21'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 11:51'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:24:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0403c08d-c547-4d19-91a7-80f0d69e99e7'	System	08 Aug 2020 00:28:39
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 00:28:39

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:24:40', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0403c08d-c547-4d19-91a7-80f0d69e99e7' User entered 'No (N)'	System	08 Aug 2020 00:28:39
	System	08 Aug 2020 00:28:39

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:27:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0403c08d-c547-4d19-91a7-80f0d69e99e7' User entered 'No (N)'	System	08 Aug 2020 00:28:39
	System	08 Aug 2020 00:28:39

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:28:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0403c08d-c547-4d19-91a7-80f0d69e99e7' User entered 'None (1)'	System	08 Aug 2020 00:28:39
	System	08 Aug 2020 00:28:39

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:28:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0403c08d-c547-4d19-91a7-80f0d69e99e7' User entered '07 Aug 2020 19:28'	System	08 Aug 2020 00:28:39
	System	08 Aug 2020 00:28:39

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 12:46'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 2'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:34:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f1c85c-1d8e-4e05-8e5c-da03c0962724'	System	09 Aug 2020 00:34:56
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 00:34:56

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:34:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f1c85c-1dbe-4e05-8e5c-da03c0962724'	System	09 Aug 2020 00:34:56
User entered 'No (N)'	System	09 Aug 2020 00:34:56

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:34:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f1c85c-1dbe-4e05-8e5c-da03c0962724'	System	09 Aug 2020 00:34:56
User entered 'No (N)'	System	09 Aug 2020 00:34:56

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:34:40', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f1c85c-1d8e-4e05-8e5c-da03c0962724'	System	09 Aug 2020 00:34:56
User entered 'None (1)'	System	09 Aug 2020 00:34:56

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:34:54', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f1c85c-1d8e-4e05-8e5c-da03c0962724' User entered '08 Aug 2020 19:34'	System	09 Aug 2020 00:34:56
	System	09 Aug 2020 00:34:56

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 3'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '606bce8b-aa3e-4e7f-a148-36f59f206d7c'	System	10 Aug 2020 01:46:00
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 01:46:00

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '606bce8b-aa3e-4e7f-a148-36f59f206d7c' User entered 'No (N)'	System	10 Aug 2020 01:46:00
	System	10 Aug 2020 01:46:00

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '606bce8b-aa3e-4e7f-a148-36f59f206d7c' User entered 'No (N)'	System	10 Aug 2020 01:46:00
	System	10 Aug 2020 01:46:00

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:34', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '606bce8b-aa3e-4e7f-a148-36f59f206d7c' User entered 'None (1)'	System	10 Aug 2020 01:46:00
	System	10 Aug 2020 01:46:00

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:45:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '606bce8b-aa3e-4e7f-a148-36f59f206d7c' User entered '09 Aug 2020 20:45'	System	10 Aug 2020 01:46:00
	System	10 Aug 2020 01:46:00

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 4'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6b5e059c-cdb6-4163-bcc0-5a31bf01eb29'	System	11 Aug 2020 01:02:47
User entered 'None (1)'	System	11 Aug 2020 01:02:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6b5e059c-cdb6-4163-bcc0-5a31bf01eb29'	System	11 Aug 2020 01:02:47
User entered 'No (N)'	System	11 Aug 2020 01:02:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:25', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6b5e059c-cdb6-4163-bcc0-5a31bf01eb29' User entered 'No (N)'	System	11 Aug 2020 01:02:47
	System	11 Aug 2020 01:02:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6b5e059c-cdb6-4163-bcc0-5a31bf01eb29'	System	11 Aug 2020 01:02:47
User entered 'None (1)'	System	11 Aug 2020 01:02:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:45', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6b5e059c-cdb6-4163-bcc0-5a31bf01eb29' User entered '10 Aug 2020 20:02'	System	11 Aug 2020 01:02:47
	System	11 Aug 2020 01:02:47

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 5'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab60a8cd-0ffe-479c-9d3d-867fc1bd2123'	System	12 Aug 2020 00:45:14
User entered 'None (1)'	System	12 Aug 2020 00:45:14

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:50', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab60a8cd-0ffe-479c-9d3d-867fc1bd2123'	System	12 Aug 2020 00:45:14
User entered 'No (N)'	System	12 Aug 2020 00:45:14

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab60a8cd-0ffe-479c-9d3d-867fc1bd2123'	System	12 Aug 2020 00:45:14
User entered 'No (N)'	System	12 Aug 2020 00:45:14

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:44:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab60a8cd-0ffe-479c-9d3d-867fc1bd2123'	System	12 Aug 2020 00:45:14
User entered 'None (1)'	System	12 Aug 2020 00:45:14

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab60a8cd-0ffe-479c-9d3d-867fc1bd2123'	System	12 Aug 2020 00:45:14
User entered '11 Aug 2020 19:45'	System	12 Aug 2020 00:45:14

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 6'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:50:49', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '07b0eeb8-3b70-428a-9116-9c46547147b5'	System	13 Aug 2020 00:51:35
User entered 'None (1)'	System	13 Aug 2020 00:51:35

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:50:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '07b0eeb8-3b70-428a-9116-9c46547147b5' User entered 'No (N)'	System	13 Aug 2020 00:51:35
	System	13 Aug 2020 00:51:35

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '07b0eeb8-3b70-428a-9116-9c46547147b5'	System	13 Aug 2020 00:51:35
User entered 'No (N)'	System	13 Aug 2020 00:51:35

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '07b0eeb8-3b70-428a-9116-9c46547147b5'	System	13 Aug 2020 00:51:35
User entered 'None (1)'	System	13 Aug 2020 00:51:35

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '07b0eeb8-3b70-428a-9116-9c46547147b5' User entered '12 Aug 2020 19:51'	System	13 Aug 2020 00:51:35
	System	13 Aug 2020 00:51:35

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 7'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c7b6b8c1-a082-4439-a9a2-4a4c0ca149fd'	System	14 Aug 2020 00:54:08
User entered 'None (1)'	System	14 Aug 2020 00:54:08

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:48', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c7b6b8c1-a082-4439-a9a2-4a4c0ca149fd' User entered 'No (N)'	System	14 Aug 2020 00:54:08
	System	14 Aug 2020 00:54:08

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c7b6b8c1-a082-4439-a9a2-4a4c0ca149fd' User entered 'No (N)'	System	14 Aug 2020 00:54:08
	System	14 Aug 2020 00:54:08

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:53:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c7b6b8c1-a082-4439-a9a2-4a4c0ca149fd'	System	14 Aug 2020 00:54:08
User entered 'None (1)'	System	14 Aug 2020 00:54:08

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c7b6b8c1-a082-4439-a9a2-4a4c0ca149fd' User entered '13 Aug 2020 19:54'	System	14 Aug 2020 00:54:08
	System	14 Aug 2020 00:54:08

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:37:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:37:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered 'None (0)'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c'	System	07 Aug 2020 14:38:50
User entered 'No (N)'	System	07 Aug 2020 14:38:50

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T09:38:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60aa8631-a727-4e81-9294-3d0089a7925c' User entered '07 Aug 2020 09:38'	System	07 Aug 2020 14:38:50
	System	07 Aug 2020 14:38:50



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 09:21'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 11:51'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:28:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:28:51', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:28:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:29:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:29:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:29:08', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'None (0)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:29:16', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered 'No (N)'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-07T19:29:32', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '4ab3e55b-1cb5-4eff-b051-4b6ed4755538' User entered '07 Aug 2020 19:29'	System	08 Aug 2020 00:32:42
	System	08 Aug 2020 00:32:42

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Aug 2020 12:46'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 2'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:16', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'None (0)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered 'No (N)'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-08T19:35:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ffc491b8-e2b8-4369-bdbd-3031c68dc2e4' User entered '08 Aug 2020 19:35'	System	09 Aug 2020 00:35:47
	System	09 Aug 2020 00:35:47

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 3'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:08', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:18', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'None (0)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered 'No (N)'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-09T20:46:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '81fee256-0978-45b3-8d70-638a296044fe' User entered '09 Aug 2020 20:46'	System	10 Aug 2020 01:46:41
	System	10 Aug 2020 01:46:41

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 4'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:02:55', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'None (0)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered 'No (N)'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-10T20:03:36', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b14abd92-b9bb-4fef-891d-ce46090eddd9' User entered '10 Aug 2020 20:03'	System	11 Aug 2020 01:03:37
	System	11 Aug 2020 01:03:37

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 5'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:14', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:29', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'None (0)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered 'No (N)'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-11T19:45:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '055cdce7-e241-47d4-b172-787978eba2fc' User entered '11 Aug 2020 19:45'	System	12 Aug 2020 00:46:02
	System	12 Aug 2020 00:46:02

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 14:05:31



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 6'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec'	System	13 Aug 2020 00:52:25
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered 'None (0)'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:47', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered 'None (0)'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:51', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered 'None (0)'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:54', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered 'None (0)'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:51:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered 'None (0)'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:52:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec'	System	13 Aug 2020 00:52:25
User entered 'No (N)'	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-12T19:52:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '65991d32-b87f-498a-84df-e92bd97475ec' User entered '12 Aug 2020 19:52'	System	13 Aug 2020 00:52:25
	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 7'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367' User entered 'None (0)'	System	14 Aug 2020 00:55:27
	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:14', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367' User entered 'None (0)'	System	14 Aug 2020 00:55:27
	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367'	System	14 Aug 2020 00:55:27
User entered 'None (0)'	System	14 Aug 2020 00:55:27



US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367' User entered 'None (0)'	System	14 Aug 2020 00:55:27
	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367'	System	14 Aug 2020 00:55:27
User entered 'None (0)'	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:25', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367' User entered 'None (0)'	System	14 Aug 2020 00:55:27
	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:54:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367'	System	14 Aug 2020 00:55:27
User entered 'No (N)'	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-13T19:55:25', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '21512600-0bf1-4c14-bb24-49eab416f367' User entered '13 Aug 2020 19:55'	System	14 Aug 2020 00:55:27
	System	14 Aug 2020 00:55:27

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	13 Aug 2020 00:52:25
User entered 'Day 8'	System	13 Aug 2020 00:52:25



US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-14T19:34:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9d24767f-3ab8-4104-975f-5a7f95dad887' User entered 'No (N)'	System	15 Aug 2020 00:34:24
	System	15 Aug 2020 00:34:24

US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-08-14T19:34:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9d24767f-3ab8-4104-975f-5a7f95dad887' User entered '14 Aug 2020 19:34'	System	15 Aug 2020 00:34:24
	System	15 Aug 2020 00:34:24

US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:52:25

US3362069

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:52:25

US3362069

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) Crystal Rowell (b) (4)	14 Aug 2020 18:23:12

US3362069

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '14 Aug 2020'	Crystal Rowell (b) (4)	14 Aug 2020 18:23:12

US3362069

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	14 Aug 2020 18:23:12

US3362069

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) Crystal Rowell (b) (4)	14 Aug 2020 18:23:12



US3362069

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	14 Aug 2020 18:23:19

US3362069

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	14 Aug 2020 18:23:19

US3362069

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:13:59

US3362069

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:13:59

US3362069

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:13:59

US3362069

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:13:59

US3362069

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:14:05

US3362069

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User entered 'I'	System	21 Aug 2020 20:14:05



US3362069

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:24:17

US3362069

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:24:17

US3362069

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:24:17

US3362069

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:24:17

US3362069

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:24:25

US3362069

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User entered '1'	System	28 Aug 2020 20:24:25

US3362069

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:05:02

US3362069

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:05:02



US3362069

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:05:02

US3362069

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'VISIT2'	System	08 Sep 2020 14:05:02

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07:37'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '4 Sep 2020 07:37'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40



US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '78'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'bpm'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '18'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'breaths/min'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '129'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	08 Sep 2020 14:07:40



US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '76'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '09:08'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '4 Sep 2020 09:08'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40



US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '62'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'bpm'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '18'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'breaths/min'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '146'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	08 Sep 2020 14:07:40



US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '84'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	08 Sep 2020 14:07:40

US3362069

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:52

US3362069

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:07:52

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 13:46:42



US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '08:26'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '04 Sep 2020 08:26'	System	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'ONCE'	System	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 13:46:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:24

US3362069

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:24



US3362069

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07:48'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:24

US3362069

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '4 Sep 2020 07:48'	System	08 Sep 2020 14:08:24

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '07:47'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '4 Sep 2020 07:47'	System	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 14:08:37



US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered empty.	System	08 Sep 2020 14:08:37

US3362069

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:08:42

US3362069

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	08 Sep 2020 14:08:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:58:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0dc83d0-a3ed-49be-993c-acc5d76ca6f' User entered 'Yes (Y)'	System	04 Sep 2020 13:58:49
	System	04 Sep 2020 13:58:49

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:58:34', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0dc83d0-a3ed-49be-993c-acc5d76ca6f' User entered '98.3'	System	04 Sep 2020 13:58:49
	System	04 Sep 2020 13:58:49



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:58:38', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0dc83d0-a3ed-49be-993c-acc5d76ca6f'	System	04 Sep 2020 13:58:49
User entered 'No (N)'	System	04 Sep 2020 13:58:49

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:58:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0dc83d0-a3ed-49be-993c-acc5d76ca6f' User entered '04 Sep 2020 08:58'	System	04 Sep 2020 13:58:49
	System	04 Sep 2020 13:58:49

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 08:46'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 11:16'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:20:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499' User entered 'Yes (Y)'	System	05 Sep 2020 02:25:26
	System	05 Sep 2020 02:25:26

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:20:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499' User entered '99.0'	System	05 Sep 2020 02:25:26
	System	05 Sep 2020 02:25:26

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:21:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499'	System	05 Sep 2020 02:25:26
User entered 'Yes (Y)'	System	05 Sep 2020 02:25:26



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient contacted. ConMed log updated.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:26:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 20:01:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:25:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499'	System	05 Sep 2020 02:25:26
User entered '1'	System	05 Sep 2020 02:25:26

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:25:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499'	System	05 Sep 2020 02:25:26
User entered '0'	System	05 Sep 2020 02:25:26

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:25:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2e9e1e99-c41d-4974-b25f-d61c01ca3499'	System	05 Sep 2020 02:25:26
User entered '04 Sep 2020 21:25'	System	05 Sep 2020 02:25:26

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 12:11'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 2'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149'	System	06 Sep 2020 00:25:58
User entered 'Yes (Y)'	System	06 Sep 2020 00:25:58

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149'	System	06 Sep 2020 00:25:58
User entered '98.2'	System	06 Sep 2020 00:25:58



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149'	System	06 Sep 2020 00:25:58
User entered 'Yes (Y)'	System	06 Sep 2020 00:25:58

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted. ConMed log updated. ' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:26:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 20:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149'	System	06 Sep 2020 00:25:58
User entered '1'	System	06 Sep 2020 00:25:58

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149' User entered '0'	System	06 Sep 2020 00:25:58
	System	06 Sep 2020 00:25:58

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:25:54', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e85692f7-caad-4ce7-a3ac-2a7222999149' User entered '05 Sep 2020 19:25'	System	06 Sep 2020 00:25:58
	System	06 Sep 2020 00:25:58

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 3'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:56:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a09e69d5-ff13-4302-a199-3fe561aa9ab3' User entered 'Yes (Y)'	System	06 Sep 2020 21:57:02
	System	06 Sep 2020 21:57:02



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:56:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a09e69d5-ff13-4302-a199-3fe561aa9ab3' User entered '98.3'	System	06 Sep 2020 21:57:02
	System	06 Sep 2020 21:57:02

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:56:34', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a09e69d5-ff13-4302-a199-3fe561aa9ab3'	System	06 Sep 2020 21:57:02
User entered 'No (N)'	System	06 Sep 2020 21:57:02

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:56:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a09e69d5-ff13-4302-a199-3fe561aa9ab3' User entered '06 Sep 2020 16:56'	System	06 Sep 2020 21:57:02
	System	06 Sep 2020 21:57:02

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 4'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:53:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83068957-6ec9-476f-8241-8e9acedaf214' User entered 'Yes (Y)'	System	08 Sep 2020 01:54:22
	System	08 Sep 2020 01:54:22

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83068957-6ec9-476f-8241-8e9acedaf214' User entered '98.3'	System	08 Sep 2020 01:54:22
	System	08 Sep 2020 01:54:22



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83068957-6ec9-476f-8241-8e9acedaf214'	System	08 Sep 2020 01:54:22
User entered 'No (N)'	System	08 Sep 2020 01:54:22

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83068957-6ec9-476f-8241-8e9acedaf214'	System	08 Sep 2020 01:54:22
User entered '07 Sep 2020 20:54'	System	08 Sep 2020 01:54:22

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 5'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:57:08', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '76a09244-9be3-46d1-a5d6-f18a0ea36192' User entered 'Yes (Y)'	System	09 Sep 2020 09:58:45
	System	09 Sep 2020 09:58:45

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '76a09244-9be3-46d1-a5d6-f18a0ea36192' User entered '96.3'	System	09 Sep 2020 09:58:45
	System	09 Sep 2020 09:58:45

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '76a09244-9be3-46d1-a5d6-f18a0ea36192'	System	09 Sep 2020 09:58:45
User entered 'No (N)'	System	09 Sep 2020 09:58:45



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '76a09244-9be3-46d1-a5d6-f18a0ea36192' User entered '09 Sep 2020 04:58'	System	09 Sep 2020 09:58:45
	System	09 Sep 2020 09:58:45

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 6'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:12:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e040e42c-715a-453c-a756-aca3631b14e0' User entered 'Yes (Y)'	System	10 Sep 2020 01:13:04
	System	10 Sep 2020 01:13:04

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:12:50', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e040e42c-715a-453c-a756-aca3631b14e0' User entered '98.2'	System	10 Sep 2020 01:13:04
	System	10 Sep 2020 01:13:04

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:12:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e040e42c-715a-453c-a756-aca3631b14e0'	System	10 Sep 2020 01:13:04
User entered 'No (N)'	System	10 Sep 2020 01:13:04

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:12:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e040e42c-715a-453c-a756-aca3631b14e0' User entered '09 Sep 2020 20:12'	System	10 Sep 2020 01:13:04
	System	10 Sep 2020 01:13:04



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 7'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:30:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e9619387-7a89-4b92-808b-6e21ffdef8f9'	System	11 Sep 2020 01:31:35
User entered 'Yes (Y)'	System	11 Sep 2020 01:31:35

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e9619387-7a89-4b92-808b-6e21ffdef8f9'	System	11 Sep 2020 01:31:35
User entered '97.6'	System	11 Sep 2020 01:31:35

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e9619387-7a89-4b92-808b-6e21ffdef8f9'	System	11 Sep 2020 01:31:35
User entered 'No (N)'	System	11 Sep 2020 01:31:35

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:32', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e9619387-7a89-4b92-808b-6e21ffdef8f9'	System	11 Sep 2020 01:31:35
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 01:31:35

US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 13:46:42



US3362069

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:59:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6a948413-af1c-455d-889d-0e6180c4482b' User entered 'None (1)'	System	04 Sep 2020 13:59:43
	System	04 Sep 2020 13:59:43

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:59:17', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6a948413-af1c-455d-889d-0e6180c4482b' User entered 'No (N)'	System	04 Sep 2020 13:59:43
	System	04 Sep 2020 13:59:43

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:59:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6a948413-af1c-455d-889d-0e6180c4482b' User entered 'No (N)'	System	04 Sep 2020 13:59:43
	System	04 Sep 2020 13:59:43

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:59:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6a948413-af1c-455d-889d-0e6180c4482b' User entered 'None (1)'	System	04 Sep 2020 13:59:43
	System	04 Sep 2020 13:59:43

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T08:59:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '6a948413-af1c-455d-889d-0e6180c4482b' User entered '04 Sep 2020 08:59'	System	04 Sep 2020 13:59:43
	System	04 Sep 2020 13:59:43

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 08:46'	System	04 Sep 2020 13:46:42



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 11:16'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:25:37', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5'	System	05 Sep 2020 02:30:06
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 02:30:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:25:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5' User entered 'No (N)'	System	05 Sep 2020 02:30:06
	System	05 Sep 2020 02:30:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:28:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5'	System	05 Sep 2020 02:30:06
User entered 'Yes (Y)'	System	05 Sep 2020 02:30:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:28:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5' User entered '95'	System	05 Sep 2020 02:30:06
	System	05 Sep 2020 02:30:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:28:44', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5'	System	05 Sep 2020 02:30:06
User entered 'None (1)'	System	05 Sep 2020 02:30:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:29:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '79a1d3b2-4050-4f93-ae9f-d536606091d5' User entered '04 Sep 2020 21:29'	System	05 Sep 2020 02:30:06
	System	05 Sep 2020 02:30:06



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 12:11'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 2'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:31:14
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'con med #6' (Site from DM).	Amy Thomassie (b) (4)	23 Feb 2021 22:03:40
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 17:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:26:16', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '51d05fc7-8dfb-420f-a7f0-e1cb1708e0aa'	System	06 Sep 2020 00:27:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 00:27:33

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:26:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '51d05fc7-8dfb-420f-a7f0-e1cb1708e0aa'	System	06 Sep 2020 00:27:33
User entered 'No (N)'	System	06 Sep 2020 00:27:33

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:27:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '51d05fc7-8dfb-420f-a7f0-e1cb1708e0aa'	System	06 Sep 2020 00:27:33
User entered 'No (N)'	System	06 Sep 2020 00:27:33

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:27:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '51d05fc7-8dfb-420f-a7f0-e1cb1708e0aa'	System	06 Sep 2020 00:27:33
User entered 'None (1)'	System	06 Sep 2020 00:27:33

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:27:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '51d05fc7-8dfb-420f-a7f0-e1cb1708e0aa' User entered '05 Sep 2020 19:27'	System	06 Sep 2020 00:27:33
	System	06 Sep 2020 00:27:33



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 3'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b17446b-ca1e-4982-b0c0-5e0fab0b1a8c' User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 21:57:30
	System	06 Sep 2020 21:57:30

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b17446b-ca1e-4982-b0c0-5e0fab0b1a8c' User entered 'No (N)'	System	06 Sep 2020 21:57:30
	System	06 Sep 2020 21:57:30

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b17446b-ca1e-4982-b0c0-5e0fab0b1a8c' User entered 'No (N)'	System	06 Sep 2020 21:57:30
	System	06 Sep 2020 21:57:30

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b17446b-ca1e-4982-b0c0-5e0fab0b1a8c'	System	06 Sep 2020 21:57:30
User entered 'None (1)'	System	06 Sep 2020 21:57:30

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '8b17446b-ca1e-4982-b0c0-5e0fab0b1a8c' User entered '06 Sep 2020 16:57'	System	06 Sep 2020 21:57:30
	System	06 Sep 2020 21:57:30



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 4'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '86a32029-7ce8-4eab-a8b3-98c255bb2fff'	System	08 Sep 2020 01:54:58
User entered 'None (1)'	System	08 Sep 2020 01:54:58

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '86a32029-7ce8-4eab-a8b3-98c255bb2fff' User entered 'No (N)'	System	08 Sep 2020 01:54:58
	System	08 Sep 2020 01:54:58

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '86a32029-7ce8-4eab-a8b3-98c255bb2fff' User entered 'No (N)'	System	08 Sep 2020 01:54:58
	System	08 Sep 2020 01:54:58

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '86a32029-7ce8-4eab-a8b3-98c255bb2fff'	System	08 Sep 2020 01:54:58
User entered 'None (1)'	System	08 Sep 2020 01:54:58

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:54:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '86a32029-7ce8-4eab-a8b3-98c255bb2fff' User entered '07 Sep 2020 20:54'	System	08 Sep 2020 01:54:58
	System	08 Sep 2020 01:54:58



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 5'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:49', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '66a7e3cc-6eef-4f39-afe9-41d80282a9fe'	System	09 Sep 2020 09:59:19
User entered 'None (1)'	System	09 Sep 2020 09:59:19

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:55', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '66a7e3cc-6eef-4f39-afe9-41d80282a9fe'	System	09 Sep 2020 09:59:19
User entered 'No (N)'	System	09 Sep 2020 09:59:19

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:58:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '66a7e3cc-6eef-4f39-afe9-41d80282a9fe'	System	09 Sep 2020 09:59:19
User entered 'No (N)'	System	09 Sep 2020 09:59:19

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '66a7e3cc-6eef-4f39-afe9-41d80282a9fe'	System	09 Sep 2020 09:59:19
User entered 'None (1)'	System	09 Sep 2020 09:59:19

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:18', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '66a7e3cc-6eef-4f39-afe9-41d80282a9fe' User entered '09 Sep 2020 04:59'	System	09 Sep 2020 09:59:19
	System	09 Sep 2020 09:59:19



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 6'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f67f5710-4e4b-41a3-bdae-0dca46ad7e0f'	System	10 Sep 2020 01:13:49
User entered 'None (1)'	System	10 Sep 2020 01:13:49

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:08', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f67f5710-4e4b-41a3-bdae-0dca46ad7e0f' User entered 'No (N)'	System	10 Sep 2020 01:13:49
	System	10 Sep 2020 01:13:49

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:16', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f67f5710-4e4b-41a3-bdae-0dca46ad7e0f' User entered 'No (N)'	System	10 Sep 2020 01:13:49
	System	10 Sep 2020 01:13:49

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f67f5710-4e4b-41a3-bdae-0dca46ad7e0f'	System	10 Sep 2020 01:13:49
User entered 'None (1)'	System	10 Sep 2020 01:13:49

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:47', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f67f5710-4e4b-41a3-bdae-0dca46ad7e0f' User entered '09 Sep 2020 20:13'	System	10 Sep 2020 01:13:49
	System	10 Sep 2020 01:13:49



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 7'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '97f2402d-e0f3-45ee-89b5-3f784ea85671'	System	11 Sep 2020 01:32:06
User entered 'None (1)'	System	11 Sep 2020 01:32:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '97f2402d-e0f3-45ee-89b5-3f784ea85671'	System	11 Sep 2020 01:32:06
User entered 'No (N)'	System	11 Sep 2020 01:32:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:45', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '97f2402d-e0f3-45ee-89b5-3f784ea85671' User entered 'No (N)'	System	11 Sep 2020 01:32:06
	System	11 Sep 2020 01:32:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:31:48', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '97f2402d-e0f3-45ee-89b5-3f784ea85671'	System	11 Sep 2020 01:32:06
User entered 'None (1)'	System	11 Sep 2020 01:32:06

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '97f2402d-e0f3-45ee-89b5-3f784ea85671' User entered '10 Sep 2020 20:32'	System	11 Sep 2020 01:32:06
	System	11 Sep 2020 01:32:06



US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:08', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:38', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:40', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered 'None (0)'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:47', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715'	System	04 Sep 2020 14:01:00
User entered 'No (N)'	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T09:00:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'ab2ae485-dbad-4744-9510-d679624ee715' User entered '04 Sep 2020 09:00'	System	04 Sep 2020 14:01:00
	System	04 Sep 2020 14:01:00

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 08:46'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 11:16'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d'	System	05 Sep 2020 02:31:06
User entered 'No interference with activity (1)'	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered 'None (0)'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d'	System	05 Sep 2020 02:31:06
User entered 'No interference with activity (1)'	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:28', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered 'None (0)'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered 'None (0)'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:34', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered 'None (0)'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:30:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered 'No (N)'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-04T21:31:03', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f8f03b75-52c5-4a4e-a1e2-7c7999d4e52d' User entered '04 Sep 2020 21:31'	System	05 Sep 2020 02:31:06
	System	05 Sep 2020 02:31:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '04 Sep 2020 12:11'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 13:46:42



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 2'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:30:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4'	System	06 Sep 2020 00:30:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:27:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4'	System	06 Sep 2020 00:30:54
User entered 'Some interference with activity (2)'	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:28:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4'	System	06 Sep 2020 00:30:54
User entered 'Some interference with activity (2)'	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:28:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4' User entered 'No interference with activity (1)'	System	06 Sep 2020 00:30:54
	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:28:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4' User entered 'None (0)'	System	06 Sep 2020 00:30:54
	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:28:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4'	System	06 Sep 2020 00:30:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:28:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4' User entered 'No (N)'	System	06 Sep 2020 00:30:54
	System	06 Sep 2020 00:30:54



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-05T19:30:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '5a5a25d6-3543-4532-8be4-feb3ceb26cb4' User entered '05 Sep 2020 19:30'	System	06 Sep 2020 00:30:54
	System	06 Sep 2020 00:30:54

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 3'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:37', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:40', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:43', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:45', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:47', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'None (0)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:57:50', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered 'No (N)'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-06T16:58:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'd0c4bc2c-cf83-4cec-95f8-f0012b70c0b6' User entered '06 Sep 2020 16:58'	System	06 Sep 2020 21:58:12
	System	06 Sep 2020 21:58:12

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 4'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:07', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'None (0)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered 'No (N)'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-07T20:55:32', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '73db7c7d-1686-4a05-b346-9c85de3616e2' User entered '07 Sep 2020 20:55'	System	08 Sep 2020 01:55:37
	System	08 Sep 2020 01:55:37

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 13:46:42



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 5'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:24', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:29', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:31', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:33', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'None (0)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:45', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered 'No (N)'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T04:59:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '64fcbebf-ce42-4def-bd46-1033b00c4ae3' User entered '09 Sep 2020 04:59'	System	09 Sep 2020 10:00:06
	System	09 Sep 2020 10:00:06

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 6'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:55', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:13:58', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:14:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:14:04', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:14:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered 'None (0)'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:14:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5'	System	10 Sep 2020 01:14:42
User entered 'No (N)'	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-09T20:14:40', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c040dd1b-3135-470d-a84d-aa1ae6e6b5d5' User entered '09 Sep 2020 20:14'	System	10 Sep 2020 01:14:42
	System	10 Sep 2020 01:14:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	04 Sep 2020 13:46:42
User entered 'Day 7'	System	04 Sep 2020 13:46:42



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9'	System	11 Sep 2020 01:32:50
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'None (0)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'None (0)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'None (0)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:25', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'None (0)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'None (0)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:30', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered 'No (N)'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-10T20:32:48', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1f95b6ab-ddb5-4e13-b40b-ec964e0ad7d9' User entered '10 Sep 2020 20:32'	System	11 Sep 2020 01:32:50
	System	11 Sep 2020 01:32:50



US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 13:46:42

US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	11 Sep 2020 01:32:50
User entered 'Day 8'	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-12T07:21:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '06c398c4-7262-4a19-8c8a-dd74d12dd242'	System	12 Sep 2020 12:21:12
User entered 'None (0)'	System	12 Sep 2020 12:21:12

US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-12T07:21:10', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '06c398c4-7262-4a19-8c8a-dd74d12dd242'	System	12 Sep 2020 12:21:12
User entered '12 Sep 2020 07:21'	System	12 Sep 2020 12:21:12

US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	11 Sep 2020 01:32:50
User entered 'Day 8'	System	11 Sep 2020 01:32:50



US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-12T07:21:14', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b20293ab-52ad-4e6d-985a-c1e1c65da63f' User entered 'No (N)'	System	12 Sep 2020 12:21:23
	System	12 Sep 2020 12:21:23

US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-09-12T07:21:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'b20293ab-52ad-4e6d-985a-c1e1c65da63f' User entered '12 Sep 2020 07:21'	System	12 Sep 2020 12:21:23
	System	12 Sep 2020 12:21:23

US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 01:32:50

US3362069

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:13:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 01:32:50

US3362069

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:39:04

US3362069

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:39:04

US3362069

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:39:04

US3362069

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:39:04



US3362069

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:39:12

US3362069

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User entered 'I'	System	11 Sep 2020 20:39:12

US3362069

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:18

US3362069

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:18

US3362069

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:18

US3362069

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:18

US3362069

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:24

US3362069

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:45
User entered 'I'	System	18 Sep 2020 14:01:24



US3362069

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:22:44

US3362069

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:22:44

US3362069

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:22:44

US3362069

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:22:44

US3362069

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:57:11

US3362069

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	02 Oct 2020 13:57:11

US3362069

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:39

US3362069

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '2 Oct 2020'	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:58:39



US3362069

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Clinic (Clinic)'	Amy Thomassie (b) (4)	02 Oct 2020 13:58:39

US3362069

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'VISIT3'	System	02 Oct 2020 13:58:39

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '02 Oct 2020'	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '08:20'	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '02 Oct 2020 08:20'	System	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered '36.8' C	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered 'Oral (Oral)'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20



US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered empty.	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered '71'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'bpm'	System	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered '18'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'breaths/min'	System	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered '135'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered '72'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:58:20



US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered 'mmHg'	System	02 Oct 2020 13:58:20

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48

US3362069

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48

US3362069

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:58:56

US3362069

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '2 Oct 2020'	Amy Thomassie (b) (4)	02 Oct 2020 13:58:56

US3362069

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	02 Oct 2020 13:59:40

US3362069

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '2 Oct 2020'	Amy Thomassie (b) (4)	02 Oct 2020 13:59:40

US3362069

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered '08:27'	Amy Thomassie (b) (4)	02 Oct 2020 13:59:40



US3362069

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '2 Oct 2020 08:27'	System	02 Oct 2020 13:59:40

US3362069

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:09
User entered 'Yes (Y)'	(b) (4) Amy Thomassie (b) (4)	02 Oct 2020 13:59:56

US3362069

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	02 Oct 2020 13:59:56

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 64'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-07T04:50:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83479f56-74a2-48a1-9763-b316f0cf77e0'	System	07 Oct 2020 09:51:28
User entered 'No (N)'	System	07 Oct 2020 09:51:28

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-07T04:51:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83479f56-74a2-48a1-9763-b316f0cf77e0'	System	07 Oct 2020 09:51:28
User entered 'No (N)'	System	07 Oct 2020 09:51:28

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-07T04:51:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '83479f56-74a2-48a1-9763-b316f0cf77e0' User entered '07 Oct 2020 04:51:26'	System	07 Oct 2020 09:51:28
	System	07 Oct 2020 09:51:28

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 14:05:31



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 71'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-16T12:00:37', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7e54ba70-2ab6-464d-a475-c42fddc148cd'	System	16 Oct 2020 17:00:58
User entered 'No (N)'	System	16 Oct 2020 17:00:58

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-16T12:00:43', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7e54ba70-2ab6-464d-a475-c42fddc148cd'	System	16 Oct 2020 17:00:58
User entered 'No (N)'	System	16 Oct 2020 17:00:58

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C747613-9C3B-47E3-88E6-33E00A70A3FC)', Time: '2020-10-16T12:00:52', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7e54ba70-2ab6-464d-a475-c42fddc148cd' User entered '16 Oct 2020 12:00:52'	System	16 Oct 2020 17:00:58
	System	16 Oct 2020 17:00:58

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 78'	System	07 Aug 2020 14:05:31



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:36:41
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 92'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-05T10:46:06', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04c1d7e3-ce48-4e96-8c10-41c44fc491c7'	System	05 Nov 2020 16:46:23
User entered 'No (N)'	System	05 Nov 2020 16:46:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-05T10:46:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04c1d7e3-ce48-4e96-8c10-41c44fc491c7'	System	05 Nov 2020 16:46:23
User entered 'No (N)'	System	05 Nov 2020 16:46:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-05T10:46:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '04c1d7e3-ce48-4e96-8c10-41c44fc491c7' User entered '05 Nov 2020 10:46:21'	System	05 Nov 2020 16:46:23
	System	05 Nov 2020 16:46:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 14:05:31



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 99'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-11T14:27:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a7d77b53-a82a-4097-8212-7b0270635b13'	System	11 Nov 2020 20:28:23
User entered 'No (N)'	System	11 Nov 2020 20:28:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-11T14:28:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a7d77b53-a82a-4097-8212-7b0270635b13'	System	11 Nov 2020 20:28:23
User entered 'No (N)'	System	11 Nov 2020 20:28:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-11T14:28:21', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a7d77b53-a82a-4097-8212-7b0270635b13' User entered '11 Nov 2020 14:28:21'	System	11 Nov 2020 20:28:23
	System	11 Nov 2020 20:28:23

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered 'Day 106'	System	07 Aug 2020 14:05:31



US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-18T12:48:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '730b4573-8b66-4832-90f5-92628fe199d2'	System	18 Nov 2020 18:48:40
User entered 'No (N)'	System	18 Nov 2020 18:48:40

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-18T12:48:19', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '730b4573-8b66-4832-90f5-92628fe199d2'	System	18 Nov 2020 18:48:40
User entered 'No (N)'	System	18 Nov 2020 18:48:40

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-18T12:48:34', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '730b4573-8b66-4832-90f5-92628fe199d2' User entered '18 Nov 2020 12:48:34'	System	18 Nov 2020 18:48:40
	System	18 Nov 2020 18:48:40

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 14:05:31

US3362069

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:24
Data entry locked.	System	07 Aug 2020 14:05:31
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 14:05:31

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-23T20:18:18', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '89adf814-98c9-4192-af83-c8ec9ff4b8f8'	System	24 Nov 2020 02:18:59
User entered 'No (N)'	System	24 Nov 2020 02:18:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-23T20:18:33', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '89adf814-98c9-4192-af83-c8ec9ff4b8f8'	System	24 Nov 2020 02:18:59
User entered 'No (N)'	System	24 Nov 2020 02:18:59



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-23T20:18:57', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '89adf814-98c9-4192-af83-c8ec9ff4b8f8' User entered '23 Nov 2020 20:18:57'	System	24 Nov 2020 02:18:59
	System	24 Nov 2020 02:18:59

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-29T19:12:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0dc76461-3ee1-4bae-b8b5-0c887982a0f9' User entered 'No (N)'	System	30 Nov 2020 01:13:11
	System	30 Nov 2020 01:13:11

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-29T19:13:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0dc76461-3ee1-4bae-b8b5-0c887982a0f9' User entered 'No (N)'	System	30 Nov 2020 01:13:11
	System	30 Nov 2020 01:13:11

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-11-29T19:13:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '0dc76461-3ee1-4bae-b8b5-0c887982a0f9' User entered '29 Nov 2020 19:13:09'	System	30 Nov 2020 01:13:11
	System	30 Nov 2020 01:13:11

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-06T06:43:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '44235bc1-191e-46ba-89fc-ea70e78c3cef'	System	06 Dec 2020 12:44:10
User entered 'No (N)'	System	06 Dec 2020 12:44:10

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-06T06:43:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '44235bc1-191e-46ba-89fc-ea70e78c3cef'	System	06 Dec 2020 12:44:10
User entered 'No (N)'	System	06 Dec 2020 12:44:10

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-06T06:44:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '44235bc1-191e-46ba-89fc-ea70e78c3cef' User entered '06 Dec 2020 06:44:05'	System	06 Dec 2020 12:44:10
	System	06 Dec 2020 12:44:10

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:44:39', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143'	System	13 Dec 2020 12:45:52
User entered 'Yes (Y)'	System	13 Dec 2020 12:45:52

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:44:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143'	System	13 Dec 2020 12:45:52
User entered 'No (N)'	System	13 Dec 2020 12:45:52

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:45:01', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143'	System	13 Dec 2020 12:45:52
User entered 'No (N)'	System	13 Dec 2020 12:45:52

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:45:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143'	System	13 Dec 2020 12:45:52
User entered 'Yes (Y)'	System	13 Dec 2020 12:45:52

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:45:27', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143'	System	13 Dec 2020 12:45:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 12:45:52

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-13T06:45:44', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '3a2581a8-9528-4b3d-bab7-002bf5236143' User entered '13 Dec 2020 06:45:44'	System	13 Dec 2020 12:45:52
	System	13 Dec 2020 12:45:52

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-20T06:51:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f0c13c8e-96cc-4acf-9967-52cfbc2b9be4'	System	20 Dec 2020 12:52:16
User entered 'No (N)'	System	20 Dec 2020 12:52:16

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-20T06:52:05', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f0c13c8e-96cc-4acf-9967-52cfbc2b9be4'	System	20 Dec 2020 12:52:16
User entered 'No (N)'	System	20 Dec 2020 12:52:16

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-20T06:52:15', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f0c13c8e-96cc-4acf-9967-52cfbc2b9be4' User entered '20 Dec 2020 06:52:15'	System	20 Dec 2020 12:52:16
	System	20 Dec 2020 12:52:16

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-27T11:38:26', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e182fa6a-ffc7-429c-9c0e-aac3819d0e74'	System	27 Dec 2020 17:38:45
User entered 'No (N)'	System	27 Dec 2020 17:38:45



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-27T11:38:33', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e182fa6a-ffc7-429c-9c0e-aac3819d0e74'	System	27 Dec 2020 17:38:45
User entered 'No (N)'	System	27 Dec 2020 17:38:45

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2020-12-27T11:38:41', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'e182fa6a-ffc7-429c-9c0e-aac3819d0e74'	System	27 Dec 2020 17:38:45
User entered '27 Dec 2020 11:38:41'	System	27 Dec 2020 17:38:45

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-05T21:03:43', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '59d55654-a9d7-44b7-89f7-e9ff831b456b'	System	06 Jan 2021 10:47:22
User entered 'No (N)'	System	06 Jan 2021 10:47:22

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-05T21:03:53', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '59d55654-a9d7-44b7-89f7-e9ff831b456b'	System	06 Jan 2021 10:47:22
User entered 'No (N)'	System	06 Jan 2021 10:47:22

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-05T21:04:14', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '59d55654-a9d7-44b7-89f7-e9ff831b456b' User entered '05 Jan 2021 21:04:14'	System	06 Jan 2021 10:47:22
	System	06 Jan 2021 10:47:22



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-10T07:43:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '10a02d62-890b-40c7-93e6-0ae9bb10c76c'	System	10 Jan 2021 13:43:25
User entered 'No (N)'	System	10 Jan 2021 13:43:25

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-10T07:43:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '10a02d62-890b-40c7-93e6-0ae9bb10c76c'	System	10 Jan 2021 13:43:25
User entered 'No (N)'	System	10 Jan 2021 13:43:25

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-10T07:43:23', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '10a02d62-890b-40c7-93e6-0ae9bb10c76c' User entered '10 Jan 2021 07:43:23'	System	10 Jan 2021 13:43:25
	System	10 Jan 2021 13:43:25

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-18T06:13:56', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60f8db00-c06f-43c2-9ab5-b0aed1c1bcff'	System	18 Jan 2021 12:15:02
User entered 'No (N)'	System	18 Jan 2021 12:15:02

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-18T06:14:48', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60f8db00-c06f-43c2-9ab5-b0aed1c1bcff'	System	18 Jan 2021 12:15:02
User entered 'No (N)'	System	18 Jan 2021 12:15:02

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-18T06:14:59', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '60f8db00-c06f-43c2-9ab5-b0aed1c1bcff' User entered '18 Jan 2021 06:14:59'	System	18 Jan 2021 12:15:02
	System	18 Jan 2021 12:15:02

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-24T06:30:25', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2b6cd756-9f5e-4ec8-91cc-d3bde41403e4'	System	24 Jan 2021 12:31:21
User entered 'No (N)'	System	24 Jan 2021 12:31:21



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-24T06:30:33', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2b6cd756-9f5e-4ec8-91cc-d3bde41403e4'	System	24 Jan 2021 12:31:21
User entered 'Yes (Y)'	System	24 Jan 2021 12:31:21

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-24T06:30:54', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2b6cd756-9f5e-4ec8-91cc-d3bde41403e4'	System	24 Jan 2021 12:31:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 12:31:21

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-01-24T06:31:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2b6cd756-9f5e-4ec8-91cc-d3bde41403e4' User entered '24 Jan 2021 06:31:11'	System	24 Jan 2021 12:31:21
	System	24 Jan 2021 12:31:21

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-03T15:13:13', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1d977272-72ba-4bd1-9ac9-d9bac2dab1ee'	System	03 Feb 2021 21:13:50
User entered 'No (N)'	System	03 Feb 2021 21:13:50

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-03T15:13:22', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1d977272-72ba-4bd1-9ac9-d9bac2dab1ee'	System	03 Feb 2021 21:13:50
User entered 'No (N)'	System	03 Feb 2021 21:13:50



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-03T15:13:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1d977272-72ba-4bd1-9ac9-d9bac2dab1ee' User entered '03 Feb 2021 15:13:46'	System	03 Feb 2021 21:13:50
	System	03 Feb 2021 21:13:50

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-07T09:26:35', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2565255e-74ff-4305-81c5-12547f89409f'	System	07 Feb 2021 15:26:50
User entered 'No (N)'	System	07 Feb 2021 15:26:50

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-07T09:26:41', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2565255e-74ff-4305-81c5-12547f89409f'	System	07 Feb 2021 15:26:50
User entered 'No (N)'	System	07 Feb 2021 15:26:50

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-07T09:26:46', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '2565255e-74ff-4305-81c5-12547f89409f' User entered '07 Feb 2021 09:26:46'	System	07 Feb 2021 15:26:50
	System	07 Feb 2021 15:26:50

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-16T09:25:42', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c2e9f16d-37cb-46c7-860f-a839909ccee0'	System	16 Feb 2021 15:26:23
User entered 'No (N)'	System	16 Feb 2021 15:26:23

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-16T09:25:51', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c2e9f16d-37cb-46c7-860f-a839909ccee0'	System	16 Feb 2021 15:26:23
User entered 'Yes (Y)'	System	16 Feb 2021 15:26:23

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-16T09:26:02', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c2e9f16d-37cb-46c7-860f-a839909ccee0'	System	16 Feb 2021 15:26:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Feb 2021 15:26:23

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-16T09:26:11', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'c2e9f16d-37cb-46c7-860f-a839909ccee0' User entered '16 Feb 2021 09:26:11'	System	16 Feb 2021 15:26:23
	System	16 Feb 2021 15:26:23

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-21T08:06:09', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '85b6ec61-400f-4994-a06a-baf129330d3c'	System	21 Feb 2021 14:06:22
User entered 'No (N)'	System	21 Feb 2021 14:06:22

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-21T08:06:12', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '85b6ec61-400f-4994-a06a-baf129330d3c'	System	21 Feb 2021 14:06:22
User entered 'No (N)'	System	21 Feb 2021 14:06:22

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-21T08:06:20', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '85b6ec61-400f-4994-a06a-baf129330d3c' User entered '21 Feb 2021 08:06:20'	System	21 Feb 2021 14:06:22
	System	21 Feb 2021 14:06:22

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-28T07:12:26-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'cdc3dfe0-d9bc-40b8-89a7-d94b59eed42b'	System	28 Feb 2021 13:12:43
User entered 'No (N)'	System	28 Feb 2021 13:12:43



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-28T07:12:29-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'cdc3dfe0-d9bc-40b8-89a7-d94b59eed42b'	System	28 Feb 2021 13:12:43
User entered 'No (N)'	System	28 Feb 2021 13:12:43

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-28T07:12:41-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'cdc3dfe0-d9bc-40b8-89a7-d94b59eed42b' User entered '28 Feb 2021 13:12:41'	System	28 Feb 2021 13:12:43
	System	28 Feb 2021 13:12:43

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-09T12:00:40-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1cb75c13-30c2-4013-891e-3dcc5aee0b80'	System	09 Mar 2021 18:01:58
User entered 'No (N)'	System	09 Mar 2021 18:01:58

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-09T12:00:43-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1cb75c13-30c2-4013-891e-3dcc5aee0b80'	System	09 Mar 2021 18:01:58
User entered 'No (N)'	System	09 Mar 2021 18:01:58

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-09T12:01:04-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '1cb75c13-30c2-4013-891e-3dcc5aee0b80' User entered '09 Mar 2021 18:01:04'	System	09 Mar 2021 18:01:58
	System	09 Mar 2021 18:01:58



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-17T18:17:05-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '234351a5-5d7e-4d35-93de-3ad81438f37e' User entered 'No (N)'	System	17 Mar 2021 23:17:32
	System	17 Mar 2021 23:17:32

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-17T18:17:11-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '234351a5-5d7e-4d35-93de-3ad81438f37e' User entered 'No (N)'	System	17 Mar 2021 23:17:32
	System	17 Mar 2021 23:17:32

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-17T18:17:29-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '234351a5-5d7e-4d35-93de-3ad81438f37e' User entered '17 Mar 2021 23:17:29'	System	17 Mar 2021 23:17:32
	System	17 Mar 2021 23:17:32

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-21T05:55:36-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '26b51819-26ce-4fa1-98fb-3cd54a84304d'	System	21 Mar 2021 10:55:53
User entered 'No (N)'	System	21 Mar 2021 10:55:53

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-21T05:55:44-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '26b51819-26ce-4fa1-98fb-3cd54a84304d'	System	21 Mar 2021 10:55:53
User entered 'No (N)'	System	21 Mar 2021 10:55:53

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-21T05:55:47-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '26b51819-26ce-4fa1-98fb-3cd54a84304d' User entered '21 Mar 2021 10:55:47'	System	21 Mar 2021 10:55:53
	System	21 Mar 2021 10:55:53

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-28T10:30:36-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '95976e10-0334-4b8c-89b1-7f0414669fe7'	System	28 Mar 2021 15:31:06
User entered 'No (N)'	System	28 Mar 2021 15:31:06



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-28T10:30:39-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '95976e10-0334-4b8c-89b1-7f0414669fe7'	System	28 Mar 2021 15:31:06
User entered 'No (N)'	System	28 Mar 2021 15:31:06

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-03-28T10:30:59-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '95976e10-0334-4b8c-89b1-7f0414669fe7' User entered '28 Mar 2021 10:30:59'	System	28 Mar 2021 15:31:06
	System	28 Mar 2021 15:31:06

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-04T12:14:21-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f990f3a1-7d1c-4eef-b1a4-d1515aa53c02'	System	04 Apr 2021 17:14:37
User entered 'No (N)'	System	04 Apr 2021 17:14:37

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-04T12:14:28-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f990f3a1-7d1c-4eef-b1a4-d1515aa53c02'	System	04 Apr 2021 17:14:37
User entered 'No (N)'	System	04 Apr 2021 17:14:37

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-04T12:14:32-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'f990f3a1-7d1c-4eef-b1a4-d1515aa53c02'	System	04 Apr 2021 17:14:37
User entered '04 Apr 2021 12:14:32'	System	04 Apr 2021 17:14:37



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-13T10:01:17-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '18119f66-cfcb-4d0f-992f-3ea7a4dd78a6'	System	13 Apr 2021 15:01:30
User entered 'No (N)'	System	13 Apr 2021 15:01:30

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-13T10:01:19-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '18119f66-cfcb-4d0f-992f-3ea7a4dd78a6'	System	13 Apr 2021 15:01:30
User entered 'No (N)'	System	13 Apr 2021 15:01:30

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-13T10:01:24-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '18119f66-cfcb-4d0f-992f-3ea7a4dd78a6' User entered '13 Apr 2021 10:01:24'	System	13 Apr 2021 15:01:30
	System	13 Apr 2021 15:01:30

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-18T06:30:36-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7d3ca0ad-3437-4643-8e11-85a0821ac63c'	System	18 Apr 2021 11:30:51
User entered 'No (N)'	System	18 Apr 2021 11:30:51

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-18T06:30:45-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7d3ca0ad-3437-4643-8e11-85a0821ac63c'	System	18 Apr 2021 11:30:51
User entered 'No (N)'	System	18 Apr 2021 11:30:51

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-18T06:30:49-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '7d3ca0ad-3437-4643-8e11-85a0821ac63c' User entered '18 Apr 2021 06:30:49'	System	18 Apr 2021 11:30:51
	System	18 Apr 2021 11:30:51

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-25T04:04:15-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a992a7db-d4d5-4028-a19f-50402bb1d87a'	System	25 Apr 2021 09:04:55
User entered 'No (N)'	System	25 Apr 2021 09:04:55



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-25T04:04:25-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a992a7db-d4d5-4028-a19f-50402bb1d87a'	System	25 Apr 2021 09:04:55
User entered 'No (N)'	System	25 Apr 2021 09:04:55

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-04-25T04:04:51-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: 'a992a7db-d4d5-4028-a19f-50402bb1d87a' User entered '25 Apr 2021 04:04:51'	System	25 Apr 2021 09:04:55
	System	25 Apr 2021 09:04:55

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-05-02T06:53:04-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9425ea9f-7c8c-4104-ae4a-f516cd1f375f'	System	02 May 2021 11:53:12
User entered 'No (N)'	System	02 May 2021 11:53:12

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-05-02T06:53:07-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9425ea9f-7c8c-4104-ae4a-f516cd1f375f'	System	02 May 2021 11:53:12
User entered 'No (N)'	System	02 May 2021 11:53:12

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-05-02T06:53:10-05:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '9425ea9f-7c8c-4104-ae4a-f516cd1f375f' User entered '02 May 2021 06:53:10'	System	02 May 2021 11:53:12
	System	02 May 2021 11:53:12



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:36:41



**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:36:41



US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:36:41

**US3362069**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:13:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:36:41

US3362069

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:36:41
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:36:41

US3362069

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-28T07:12:05-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '52825072-617b-458b-b02a-c0b4e5a7c31c'	System	28 Feb 2021 13:12:17
User entered 'No (N)'	System	28 Feb 2021 13:12:17

US3362069

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:22

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:55:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (735CCB93-0171-41BE-8E29-A09E887F90A8)', Time: '2021-02-28T07:12:15-06:00', User OID: 'PatientReportedOutcome (US3362069)', ODM File OID: '52825072-617b-458b-b02a-c0b4e5a7c31c' User entered '28 Feb 2021 13:12:15'	System	28 Feb 2021 13:12:17
	System	28 Feb 2021 13:12:17

US3362069

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:04

US3362069

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:28
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:04

US3362069

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:04



US3362069

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:04

US3362069

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:34:10

US3362069

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:48
User entered '1'	System	27 Oct 2020 19:34:10

US3362069

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:49:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 16:01:08

US3362069

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:49:15
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Dec 2020 16:01:08

US3362069

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:49:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 16:01:08

US3362069

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:49:15
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 16:01:08

US3362069

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:49:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 16:01:13



US3362069

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User entered 'I'	System	01 Dec 2020 16:01:13

US3362069

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:06:17

US3362069

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:06:17

US3362069

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:06:17

US3362069

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:06:17

US3362069

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:06:07

US3362069

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User entered '1'	System	30 Dec 2020 19:06:07

US3362069

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:02:33



US3362069

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:02:33

US3362069

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:02:33

US3362069

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:02:33

US3362069

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:02:37

US3362069

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:36
User entered '1'	System	29 Jan 2021 20:02:37

US3362069

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	19 Feb 2021 23:06:56

US3362069

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '19 Feb 2021'	(b) (4) Alexandra Caillouet (b) (4)	19 Feb 2021 23:06:56

US3362069

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	19 Feb 2021 23:06:56



US3362069

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered 'VISIT4'	System	19 Feb 2021 23:06:56

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'No (N)'	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered empty.	System	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46



US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered empty.	System	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered empty.	System	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered empty.	System	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:29:46

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered empty.	System	30 Mar 2021 18:29:46



US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10

US3362069

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:22

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10

US3362069

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	19 Feb 2021 23:07:22

US3362069

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	Alexandra Caillouet (b) (4)	19 Feb 2021 23:07:22

US3362069

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	18 Mar 2021 20:57:51

US3362069

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '19 Feb 2021'	(b) (4) Amy Thomassie (b) (4)	18 Mar 2021 20:57:51

US3362069

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered '07:48'	Amy Thomassie (b) (4) (b) (4)	18 Mar 2021 20:57:51

US3362069

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered '19 Feb 2021 07:48'	System	18 Mar 2021 20:57:51



US3362069

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	19 Feb 2021 23:07:27

US3362069

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:16:10
User entered '1'	System	19 Feb 2021 23:07:27

US3362069

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:46:10

US3362069

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:46:10

US3362069

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:46:10

US3362069

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:22

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:46:10

US3362069

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:46:15

US3362069

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:22

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 14:46:15

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US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:12

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:12

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:12

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 14:06:12

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	19 Feb 2021 02:55:37
User entered '06 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:50:05

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:50:05



US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User entered empty.	System	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:13:22

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User entered empty.	System	29 Jan 2021 14:06:49

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:07:11



US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:07:11

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '07:22'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:07:11

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User entered '29 Jan 2021 07:22'	System	29 Jan 2021 14:07:11

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:05:55

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:05:55

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '07:24'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:05:55

US3362069

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:22

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:11:36
User entered '29 Jan 2021 07:24'	System	29 Jan 2021 14:05:55

US3362069

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:13:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:11
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:50:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:22:42



US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:20:44
User entered 'USA-US112-2020-mRNA-1273-P301000014'	System	10 Dec 2020 18:18:58
User entered 'New'	(b) (4), (b) (6)	10 Dec 2020 18:18:58

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Partial bowel obstruction - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	15 Dec 2020 17:09:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 17:09:55
Data point term sent to Coder	System	15 Dec 2020 17:02:02
Coding entries removed.	Crystal Rowell (b) (4)	15 Dec 2020 17:01:47
User entered 'PARTIAL BOWEL OBSTRUCTION -ILEUM' reason for change: Data Entry Error	Crystal Rowell (b) (4)	15 Dec 2020 17:01:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 05:07:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 05:07:50
Data point term sent to Coder	System	09 Dec 2020 18:53:59
User entered 'Small Bowel Obstruction'	Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Yes (Y)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'Per CDM: Was this a Solicited Adverse Reaction? = YES. However, according to protocol 'PARTIAL BOWEL OBSTRUCTION -ILEUM' is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:32:29
Query 'Per CDM: Was this a Solicited Adverse Reaction? = YES. However, according to protocol 'PARTIAL BOWEL OBSTRUCTION -ILEUM' is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. answered with 'data error.' (Site from DM).	Alexandra Caillouet (b) (4)	15 Dec 2020 20:40:31
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	15 Dec 2020 20:40:20
User opened query 'Per CDM: Was this a Solicited Adverse Reaction? = YES. However, according to protocol 'PARTIAL BOWEL OBSTRUCTION -ILEUM' is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 20:36:52
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'No (N)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '6 Dec 2020'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:53:10



US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Crystal Rowell (b) (4)	15 Dec 2020 17:01:47
User entered 'Yes (Y)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:33:33
User entered '13 Dec 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:01:47
User entered empty.	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:10:49
User entered empty.	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the end date of 13 Dec 2020. Per medical records, subject met metrics for discharge on 11 Dec 2020, including regular bowel movements, no pain, and tolerating a regular diet. ' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:58:32
User opened query 'PV Query: Please confirm the end date of 13 Dec 2020. Per medical records, subject met metrics for discharge on 11 Dec 2020, including regular bowel movements, no pain, and tolerating a regular diet. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:07:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:43:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:26:42
User entered empty.	System	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Grade 4 (Grade 4)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Yes (Y)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '0'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '0'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	



US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:50:51
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'UPDATED' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:01:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 18:08:11
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 18:08:05
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'patient is still hospitalized at this time ' (Site from System).	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Dec 2020 18:53:10
User entered '1'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '6 Dec 2020'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:31:34
User entered '13 Dec 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	15 Dec 2020 17:01:47
User entered empty.	(b) (4) Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'No (N)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered empty.	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '0'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered '0'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
	(b) (4)	
User entered '0'	Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Crystal Rowell (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

None

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment for this AE as appropriate. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 15:47:31
Query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment for this AE as appropriate. Otherwise, clarify reason why no treatment is needed.' answered with 'updated narrative with additional information. no action taken.' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	28 Jan 2021 21:13:12
User opened query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please update to record the corresponding treatment for this AE as appropriate. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:03:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:31:58
User entered '0'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:32:04
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:31:58
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:53:36
User entered '1'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:23:16
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:32:09
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User entered '1'	(b) (4), (b) (6)	12 Jan 2021 22:31:58
	(b) (4), (b) (6)	11 Jan 2021 04:53:42
	Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 14:14:13
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:02:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:01:47
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 16:27:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:49
	(b) (4)	
User entered empty.	Crystal Rowell (b) (4)	09 Dec 2020 18:53:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:10:49
User entered 'SUBJECT CONTACTED SITE TO NOTIFY OF HOSPITALIZATION ON 06DEC2020 FOR PARTIAL BOWEL OBSTRUCTION OF ILEUM;. WILL SIGN MEDICAL RELEASE TO UPDATE CHART. No surgical or medicinal intervention required. AE resolved with bowel rest.' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	28 Jan 2021 21:12:45
User closed query ' . PV Query: Please confirm the hospital discharge date. Hospital discharge summary states 11 Dec 2020, but the EDC lists 13 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 20:35:01
Query ' . PV Query: Please confirm the hospital discharge date. Hospital discharge summary states 11 Dec 2020, but the EDC lists 13 Dec 2020. ' answered with 'per query, noted and updated. ' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 17:31:18
User opened query ' . PV Query: Please confirm the hospital discharge date. Hospital discharge summary states 11 Dec 2020, but the EDC lists 13 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:06:19
User closed query '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)	22 Dec 2020 17:34:27
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)	22 Dec 2020 17:34:25
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)	22 Dec 2020 17:34:15
User closed query 'PV Query: Please provide information on the mechanism of small intestine obstruction: mechanical or functional? ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:34:00

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'medical records redacted and sent in ' (Site from Safety).	Crystal Rowell (b) (4)	21 Dec 2020 19:03:22
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 'ID Now COVID 19 testing nasopharyngeal swab completed on 06Dec2020- negative ' (Site from Safety).	Crystal Rowell (b) (4)	21 Dec 2020 19:03:03
Query 'including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'patient was admitted to hospital 6Dec2020 treated with nasogastric tube decompression, small bowel follow through completed on day 2 of stay with contrast, passage of contrast allowed, bowel movements noted, diet advanced as tolerated' (Site from Safety).	Crystal Rowell (b) (4)	21 Dec 2020 19:01:20
Query 'PV Query: Please provide information on the mechanism of small intestine obstruction: mechanical or functional? ' answered with 'mechanical ' (Site from Safety).	Crystal Rowell (b) (4)	21 Dec 2020 18:59:16
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)	21 Dec 2020 15:39:42
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)	21 Dec 2020 15:39:22
User opened query '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)	21 Dec 2020 15:38:55
User opened query 'PV Query: Please provide information on the mechanism of small intestine obstruction: mechanical or functional? ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:38:29

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
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)	16 Dec 2020 14:14:19
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)	16 Dec 2020 14:14:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records requested' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:02:47
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 requested' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:02:34
User entered 'SUBJECT CONTACTED SITE TO NOTIFY OF HOSPITALIZATION ON 06DEC2020 FOR PARTIAL BOWEL OBSTRUCTION OF ILEUM;. WILL SIGN MEDICAL RELEASE TO UPDATE CHART.' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	15 Dec 2020 17:01:47
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)	15 Dec 2020 16:27:45
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)	15 Dec 2020 16:27:16

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject contacted site to notify of hospitalization on 06Dec2020 for bowel obstruction; anticipated discharge 07Dec2020. Will sign medical release to update chart.'	Crystal Rowell (b) (4) (b) (4)	09 Dec 2020 18:53:10

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 18:53:10

---

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 18:53:10

---

US3362069

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:53:10

---

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\\23.0.	(b) (4)	07 Apr 2021 14:16:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 14:16:34
Data point term sent to Coder	System	07 Apr 2021 14:15:39
User entered 'Dry Eyes'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Yes (Y)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '26 Mar 2021'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:14:40

---

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:14:40

---

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Related (NOT RELATED)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Related (NOT RELATED)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

None

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '1'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered '0'	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
	(b) (4)	
User entered empty.	Alexandra Caillouet	07 Apr 2021 14:14:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	07 Apr 2021 14:14:40

US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 14:14:40

---



US3362069

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:22

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 14:14:40

---

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User coded data point as SOC: Gastrointestinal disorders, HLT: Dental disorders NEC, PT: Poor dental condition, LLT: Poor dental condition - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 16:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 16:28:41
User coded data point as SOC: Gastrointestinal disorders, HLT: Dental disorders NEC, PT: Poor dental condition, LLT: Poor dental condition - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 16:27:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 16:27:55
Data point term sent to Coder	System	08 Apr 2021 16:27:29
User closed query 'CDM-Coding: Please split the reported term "POOR DENTITION (DENTAL IMPLANT)" to report each event separately to capture coding for all terms. Example: 1) POOR DENTITION 2) DENTAL IMPLANT. Thank you. ' (Site from System).	System	08 Apr 2021 16:26:28
Query 'CDM-Coding: Please split the reported term "POOR DENTITION (DENTAL IMPLANT)" to report each event separately to capture coding for all terms. Example: 1) POOR DENTITION 2) DENTAL IMPLANT. Thank you. ' answered with 'implant captured in con procedures' (Site from System).	Alexandra Caillouet (b) (4)	08 Apr 2021 16:26:28
Data point term sent to Coder	System	08 Apr 2021 16:26:28
User entered 'POOR DENTITION' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Apr 2021 16:25:55
User opened query 'CDM-Coding: Please split the reported term "POOR DENTITION (DENTAL IMPLANT)" to report each event separately to capture coding for all terms. Example: 1) POOR DENTITION 2) DENTAL IMPLANT. Thank you. ' (Site from System).	Coder Import (b) (4)	08 Apr 2021 09:43:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Apr 2021 14:16:40
User entered 'Poor dentition (dental implant)'	Alexandra Caillouet	07 Apr 2021 14:16:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '22 Jan 2021'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User entered empty.	System	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '26 Jan 2021'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User entered empty.	System	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'No (N)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36



US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36



US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '1'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered '0'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36



US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:40
User entered empty.	Alexandra Caillouet (b) (4)	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User entered '0'	System	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09
User entered '0'	System	07 Apr 2021 14:16:36

US3362069

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:16:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:13:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:54:24

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 14:59:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:59:38
Data point term sent to Coder	System	10 Aug 2020 14:55:57
User entered 'simvastatin'	(b) (4), (b) (6)	10 Aug 2020 14:55:18



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'hyperlipidemia'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '10'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 13:38:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:55:18
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:55:18

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:55:18

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:55:18

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:55:18

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 14:59:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:59:40
Data point term sent to Coder	System	10 Aug 2020 14:56:59
User entered 'lisinopril'	(b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '5'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:54:14
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at study entry' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 15:00:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:56:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 14:56:00



US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:56:00

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:56:00

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:56:00

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: RHAMNUS PURSHIANA, PRODUCTSYNONYM: CASCARA SAGRADA [RHAMNUS PURSHIANA] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	28 Sep 2020 13:39:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 13:39:36
Data point term sent to Coder	System	11 Sep 2020 20:45:32
User closed query 'DM-Coding: Please verify the spelling if it is correct please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	11 Sep 2020 20:45:05
Query 'DM-Coding: Please verify the spelling if it is correct please add active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'This is classified as a shrub.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 20:45:05
Data point term sent to Coder	System	11 Sep 2020 20:44:29
User entered 'Cascara Sagrada' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 20:44:07
User opened query 'DM-Coding: Please verify the spelling if it is correct please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:02:15
Data point term sent to Coder	System	10 Aug 2020 15:03:12
User entered 'cuscura sageda'	(b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'constipation'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '450'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:09:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 15:03:01
User entered 'un UNK 2014'	(b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:03:01

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:03:01

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:03:01

---

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:03:01

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Aug 2020 18:23:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:23:21
Data point term sent to Coder	System	10 Aug 2020 15:04:15
User entered 'testosterone'	(b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'hypogonadism'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '200'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:09:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 15:04:08
User entered 'un UNK 2017'	(b) (4), (b) (6)	10 Aug 2020 15:04:08



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:04:08

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:04:08

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:04:08

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '803 (803)'	System	10 Aug 2020 15:04:08

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 19:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 19:18:52
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	25 Sep 2020 15:15:38 25 Sep 2020 15:14:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 15:07:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 15:07:16
Data point term sent to Coder User entered 'allopurinol'	System (b) (4), (b) (6)	10 Aug 2020 15:06:17 10 Aug 2020 15:05:17



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Per DM CLR RQ: Response noted. Please review if the indication should be updated as general gout. Ensure this condition is recorded in MH ecrf so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:42:30
Query 'Per DM CLR RQ: Response noted. Please review if the indication should be updated as general gout. Ensure this condition is recorded in MH ecrf so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:14:51
User entered 'General GOUT' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:14:46
User opened query 'Per DM CLR RQ: Response noted. Please review if the indication should be updated as general gout. Ensure this condition is recorded in MH ecrf so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:32:53
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:32:53
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'variable locations per medical history' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	18 Sep 2020 21:04:46
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:14:56
User entered 'gout'	(b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '100'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 08:33:13
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	18 Sep 2020 21:06:37
User entered 'mg (mg)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	18 Sep 2020 21:05:10
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:14:36
User entered 'ug (ug)'	(b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:10:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 15:05:17
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:05:17

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:05:17

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:05:17

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:05:17

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 12:32:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 12:32:33
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Oct 2020 21:16:06 21 Oct 2020 21:15:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:08:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:08:24
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Oct 2020 20:26:39 08 Oct 2020 20:26:03

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 23:09:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 23:09:39
Data point term sent to Coder	System	11 Sep 2020 20:41:23
User entered 'Advil'	(b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Per DM CLR: Indication is ADVERSE REACTION (E-DIARY DAY 1 AND 2) TO TREAT PAIN/FEVER and Prophylaxis is YES however there is a record of ADVERSE REACTION of PAIN in the eDiary page. Please review response to "Prophylaxis", and update to NO. Otherwise provide clarification' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:20:25
Query 'Per DM CLR: Indication is ADVERSE REACTION (E-DIARY DAY 1 AND 2) TO TREAT PAIN/FEVER and Prophylaxis is YES however there is a record of ADVERSE REACTION of PAIN in the eDiary page. Please review response to "Prophylaxis", and update to NO. Otherwise provide clarification' answered with 'not ae less than 48 hours' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:16:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 21:14:58
User opened query 'Per DM CLR: Indication is ADVERSE REACTION (E-DIARY DAY 1 AND 2) TO TREAT PAIN/FEVER and Prophylaxis is YES however there is a record of ADVERSE REACTION of PAIN in the eDiary page. Please review response to "Prophylaxis", and update to NO. Otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:32:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication ADVERSE REACTION of FEVER . Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:20:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 'ADVERSE REACTION of PAIN' during this timeframe. If the ADVERSE REACTION of PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ADVERSE REACTION of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:20:12
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 'ADVERSE REACTION of PAIN' during this timeframe. If the ADVERSE REACTION of PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ADVERSE REACTION of PAIN did not meet the AE reporting criteria.' answered with 'not ae less than 48 hours' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:16:48

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication ADVERSE REACTION of FEVER . Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'not ae less than 48 hours' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:16:29
User entered 'REACTION (E-DIARY DAY 1 AND 2) TO TREAT PAIN/FEVER' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 21:15:40
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication ADVERSE REACTION of FEVER . Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:27:56
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication 'ADVERSE REACTION of PAIN' during this timeframe. If the ADVERSE REACTION of PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ADVERSE REACTION of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:27:39
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:52:14
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication. Update Con Med eCRF as appropriate.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:26:08

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'ADVERSE REACTION (E-DIARY DAY 1 AND 2) To treat pain/fever' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 20:26:03
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:10:14
User entered 'Adverse Reaction (E-diary day 1 and 2)'	(b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '200'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User entered empty.	System	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User entered empty.	System	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:47
User entered empty.	System	11 Sep 2020 20:41:05

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 15:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 15:19:51
Data point term sent to Coder	System	25 Sep 2020 15:18:45
User entered 'Advil'	(b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'lower back pain'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '200'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:18:20

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 15:18:20

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 15:18:20

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 15:18:20

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:13:56
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 08:13:56
Data point term sent to Coder	System	02 Apr 2021 14:50:22
User entered 'Ambian'	(b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '12.5'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User entered '1'	System	02 Apr 2021 14:49:29



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User entered '1'	System	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:52
User entered '804 (804)'	System	02 Apr 2021 14:49:29

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 14:52:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 14:52:49
Data point term sent to Coder	System	02 Apr 2021 14:51:23
User entered 'Amoxicillin'	(b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Tooth implant'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '500'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User entered '3'	System	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User entered '1'	System	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:57
User entered '804 (804)'	System	02 Apr 2021 14:50:34

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE, PRODUCTSYNONYM: LUNESTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Apr 2021 14:52:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 14:52:49
Data point term sent to Coder	System	02 Apr 2021 14:51:23
User entered 'Lunesta'	(b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '3'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:51:09

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 14:51:09

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 14:51:09

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:13:22

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 14:51:09

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US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: LIFITEGRAST, PRODUCTSYNONYM: XIIDRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Apr 2021 14:52:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 14:52:50
Data point term sent to Coder	System	02 Apr 2021 14:52:25
User entered 'Xiidra'	(b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Dry eyes'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Drop'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Ophthalmic'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14



US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:13:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:52:14

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:13:22**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 14:52:14

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US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 14:52:14

---

US3362069

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:13:22**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 14:52:14

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US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:13:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:11
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 16:26:57
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:22:50

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '16 Dec 2020'	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:31:42

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Mohs surgery for basal cell carcinoma'	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:31:42

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Medical History (MH)'	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:31:42

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:22

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:31:42

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered '22 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:32:23

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 16:32:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 16:32:45
User entered 'Dental Implant' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Apr 2021 16:32:45
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 16:32:23
User entered empty.	Alexandra Caillouet (b) (4)	08 Apr 2021 16:32:23

US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered 'Adverse Event (AE)'	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:32:23



US3362069

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:22

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:27
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	08 Apr 2021 16:32:23

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '10/Dec/2020 13:22'	(b) (4) System	10 Dec 2020 18:22:55



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered '1'	(b) (4), (b) (6)	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

**US3362069**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:13:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '15/Dec/2020 14:51'	(b) (4) System	15 Dec 2020 19:52:01

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:52:06
User entered '1'	(b) (4), (b) (6)	15 Dec 2020 19:52:01

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '16/Dec/2020 09:14'	(b) (4) System	16 Dec 2020 14:14:46

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 14:14:51
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 14:14:46

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '22/Dec/2020 11:35'	(b) (4) System	22 Dec 2020 17:35:56

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered '1'	(b) (4), (b) (6)	22 Dec 2020 17:35:56

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '04/Jan/2021 20:35'	(b) (4) System	04 Jan 2021 20:36:02

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:24:04
User entered '1'	(b) (4), (b) (6)	04 Jan 2021 20:36:02

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '13/Jan/2021 11:24'	(b) (4) System	13 Jan 2021 16:24:18

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:55:04
User entered 'I'	(b) (4), (b) (6)	13 Jan 2021 16:24:18

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'USA-US112-2020-MRNA-1273-P301000014'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Yes (Y)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'No (N)'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Jordan'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'Whatley'	System	10 Dec 2020 18:18:58



US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '5326 O'donovan dr'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered 'baton rouge'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:44
User entered '70808'	System	10 Dec 2020 18:18:58

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:35:49
User entered 'US'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Jan 2021 19:55:16
User entered '6'	System	13 Jan 2021 16:24:18
User entered '5'	System	04 Jan 2021 20:36:02
User entered '4'	System	22 Dec 2020 17:35:56
User entered '3'	System	16 Dec 2020 14:14:46
User entered '2'	System	15 Dec 2020 19:52:01
User entered '1'	System	10 Dec 2020 18:22:55

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:13:22

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered '29/Jan/2021 14:55'	(b) (4) System	29 Jan 2021 19:55:16

US3362069

Folder: SAE USA-US112-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:13:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:55:16