

US3542029 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:10:56

All time stamps listed in this document are displayed in GMT

US3542029

Form: Participant Creation

Data signed: (b) (4) 27 Aug 2020 15:36:23

Generated On: 10 Jun 2021 08:10:56

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[Participant ID](#)

US3542029

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

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US3542029

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

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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 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	DIABETES MELLITUS
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)	_____

US3542029

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	HYPERTENSION
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)	_____

US3542029

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	DEPRESSION
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)	_____

US3542029

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	PTSD
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)	_____

US3542029

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	OSTEOARTHRITIS IN RIGHT KNEE
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)	



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	SEASONAL ALLERGIES
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 (8)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	NEPHROLITHIASIS
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 (9)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Mar 2021 18:40:17

Generated On: 10 Jun 2021 08:10:56

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3542029

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:32
Height (xxx.x)	168 cm
Weight (xxx.x)	292 lb
BMI (xxx.x)	47.02639 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Dec 2020 19:24:46

Generated On: 10 Jun 2021 08:10:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2004

Date of last menstruation unknown False

US3542029

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Sep 2020 22:35:53

Generated On: 10 Jun 2021 08:10:56

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

WORKS FROM HOME

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Sep 2020 22:35:53

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Sep 2020 04:14:07

Generated On: 10 Jun 2021 08:10:56

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

What was the participant's randomization number? 143743

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:32
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:45
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Dec 2020 19:24:46

Generated On: 10 Jun 2021 08:10:56

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 11:15

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) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	10:54 (24 HR)
Collection date and time (derived)	20 AUG 2020 10:54

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:56	20 AUG 2020 10:56
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 27 Aug 2020 15:36:24

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 11:55

PC Open Date & Time

20 AUG 2020 11:35

PC Close Date & Time

20 AUG 2020 14:05

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**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 98.3 °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	20 AUG 2020 19:53
PC Open Date & Time	20 AUG 2020 15:00
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**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

98.4 °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

21 AUG 2020 12:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 13:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 23 AUG 2020 13:45

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:58

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 25 AUG 2020 15:58

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 26 AUG 2020 17:35

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 11:55

PC Open Date & Time

20 AUG 2020 11:35

PC Close Date & Time

20 AUG 2020 14:05

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**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

20 AUG 2020 19:52

PC Open Date & Time

20 AUG 2020 15:00

PC Close Date & Time

21 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 13:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 13:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 19:58

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 15:58

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**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 ☐

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 11:56
PC Open Date & Time	20 AUG 2020 11:35
PC Close Date & Time	20 AUG 2020 14:05

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**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 ☐



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 19:52
PC Open Date & Time	20 AUG 2020 15:00
PC Close Date & Time	21 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2720

EAB) (1725)

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 13:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2720

EAB) (1725)

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2720

EAB) (1725)



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:59
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2720

EAB) (1725)

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 15:58
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:36
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3542029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Sep 2020 15:26:54

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 15:26:54

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Sep 2020 01:40:56

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3542029

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Sep 2020 01:40:56

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Sep 2020 04:49:45

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 04:49:45

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 08:37
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:14
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3542029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

17 SEP 2020

---

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

---

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 09:44

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



US3542029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	08:59 (24 HR)
Collection date and time (derived)	17 SEP 2020 08:59

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:03	17 SEP 2020 09:03
Nasopharyngeal Swab 2	No		

US3542029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Sep 2020 15:13:53

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 10:22

PC Open Date & Time

17 SEP 2020 10:04

PC Close Date & Time

17 SEP 2020 12:34

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**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 98.2 °F

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

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

PC Time Stamp	17 SEP 2020 16:01
PC Open Date & Time	17 SEP 2020 13:29
PC Close Date & Time	18 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:12

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

19 SEP 2020 16:56

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 16:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 22 SEP 2020 12:09

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

---

PC Time Stamp 23 SEP 2020 12:05

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

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US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**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

17 SEP 2020 10:23

PC Open Date & Time

17 SEP 2020 10:04

PC Close Date & Time

17 SEP 2020 12:34

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

12

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 16:01

PC Open Date & Time

17 SEP 2020 13:29

PC Close Date & Time

18 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:13

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 16:57

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 16:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**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 ☐

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 10:23
PC Open Date & Time	17 SEP 2020 10:04
PC Close Date & Time	17 SEP 2020 12:34

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**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 ☐

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 16:02
PC Open Date & Time	17 SEP 2020 13:29
PC Close Date & Time	18 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:13
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 16:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:21
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 18:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:10
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:06
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3542029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Sep 2020 04:14:07

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 04:14:07

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Nov 2020 04:10:05

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 15:26:38

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Oct 2020 02:19:29

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3542029

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 02:19:29

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Oct 2020 18:29:32

Generated On: 10 Jun 2021 08:10:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Oct 2020 18:29:32

Generated On: 10 Jun 2021 08:10:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:28
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Oct 2020 18:29:32

Generated On: 10 Jun 2021 08:10:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3542029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Oct 2020 18:29:32

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	08:49 (24 HR)
Collection date and time (derived)	15 OCT 2020 08:49

US3542029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Oct 2020 18:29:32

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 00:57:24
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 02:36:42

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59



US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 12:01:57
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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	17 NOV 2020 19:11:05
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 11:00:21

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 21:37:16
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	12 DEC 2020 10:12:33
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 00:36:40
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 22:12:08

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:01:29

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 07:39:15
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 00:02:39

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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

23 JAN 2021 00:02:05

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 08:29:21
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 00:57:58

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 FEB 2021 00:19:20
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 08:20:46
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 00:14:17

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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

13 MAR 2021 00:02:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 21:04:13

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	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 <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 06:27:52
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	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	03 APR 2021 21:40:28
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 12:00:51
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:36:09

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 00:36:42
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

<b>TIMEPOINT</b>	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 02:41:33
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

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 ☐



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 NOV 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59
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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAR 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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03 AUG 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

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 ☐

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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03 SEP 2022 00:01

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07 SEP 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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10 SEP 2022 00:01

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14 SEP 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**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 ☐



**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542029**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3542029

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:10:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:21:07

US3542029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 21:45:17

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:45:17

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3542029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 27 Dec 2020 22:57:30

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Jan 2021 18:09:56

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Jan 2021 18:09:56

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:59:51

Generated On: 10 Jun 2021 08:10:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542029

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:59:51

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 18:06:30

Generated On: 10 Jun 2021 08:10:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:12:50

Generated On: 10 Jun 2021 08:10:56

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) \_\_\_\_\_



US3542029

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 18:06:30

Generated On: 10 Jun 2021 08:10:56

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.*

US3542029

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 18:06:30

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	18 MAR 2021 13:40

US3542029

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 18:06:30

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 20:06:22

Generated On: 10 Jun 2021 08:10:56

---

Was Contact Attempted? Yes ☒ No ☐

---

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

---

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

---

Comments LEFT VOICEMAILS AT 11:47, 14:22, 15:37

---

*If Contact Not Made, please provide Comments*

---

US3542029

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:06:22

Generated On: 10 Jun 2021 08:10:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542029

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

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*

**US3542029**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:10:56**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542029

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:10:56

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"/>



**US3542029**

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

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

**Generated On: 10 Jun 2021 08:10:56**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3542029

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

Form: Visit Date

Data signed: (b) (4) 25 Jan 2021 20:40:39

Generated On: 10 Jun 2021 08:10:56

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3542029

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:38:37

Generated On: 10 Jun 2021 08:10:56

Date of updated informed consent (dd MMM yyyy) 25 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) 25 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 \_\_\_\_\_

US3542029

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Jan 2021 20:40:39

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	25 JAN 2021 08:35

US3542029

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Jan 2021 20:40:39

Generated On: 10 Jun 2021 08:10:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	08:38
Collection Date and Time (derived)	25 JAN 2021 08:38

US3542029

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Sep 2020 15:26:54

Generated On: 10 Jun 2021 08:10:56

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

330 of 2720

EAB) (1725)

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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



US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Mar 2021 18:06:29

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID

Adverse event

ATRIAL FIBRILLATION  
(WORSENING)

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)

18 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID	USA-US084-2021-MRNA-1273-P30 1000006
Adverse event	HYPERKALEMIA DUE TO ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY
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)	18 FEB 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)	20 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	22 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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PT WITH UNDERLYING IDDM,  
HYPERTENSION,  
HYPERLIPIDEMIA,  
PAROXYSMAL ATRIAL  
FIBRILLATION, AND  
NEPHROLITHIASIS WAS  
BROUGHT TO GWU ED ON  
18-FEB-2021 AFTER BEING  
FOUND UNCONSCIOUS AT  
HOME BY DAUGHTER. SHE  
WAS FOUND TO HAVE  
HYPERKALEMIA, ACUTE  
KIDNEY INJURY,  
HYPERGLYCEMIA,  
COMMUNITY ACQUIRED  
PNEUMONIA AND ATRIAL  
FIBRILLATION (WITH RVR).  
COVID-19 PCR (DONE  
18FEB2021) WAS NEGATIVE.  
SHE WAS ADMITTED FOR  
FURTHER WORK-UP AND  
MANAGEMENT. SHE WAS  
GIVEN LOKELMA AND  
CALCIUM GLUCONATE. BLOOD  
CULTURES PERFORMED ON  
21FEB2021 WERE NEGATIVE. PT  
WAS DISCHARGED FROM  
HOSPITAL ON 22-FEB-2021.  
REASON FOR ADMISSION WAS  
HYPERKALEMIA LIKELY DUE  
TO ACUTE KIDNEY INJURY OF  
UNCERTAIN ETIOLOGY.

---

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

---

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID

Adverse event

COMMUNITY ACQUIRED  
PNEUMONIA

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)

18 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID

Adverse event

ELEVATED LACTIC ACID

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)

18 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID	
Adverse event	ABDOMINAL PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 FEB 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)	22 FEB 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 (9)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

AEID

Adverse event

ACUTE KIDNEY INJURY

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)

18 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 21 Mar 2021 18:06:29

Generated On: 10 Jun 2021 08:10:56

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 27 Aug 2020 15:36:23

Generated On: 10 Jun 2021 08:10:56

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication LORATADINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (3)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication VIIBRYD

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 30

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) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication ATORVASTATIN

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 (6)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication TRESIBA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 30

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify EVERY NIGHT

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 400

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 (10)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE, CHILLS, MYALGIA,  
ARTHRALGIA

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication AUGMENTIN (AMOXICILLIN  
500MG/CLAVULANIC ACID 125  
MG)

Prophylaxis Yes ☐  
No ☒

Indication COMMUNITY-ACQUIRED  
PNEUMONIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

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	Transdermal	<input type="checkbox"/>
	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

QHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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Name of Medication LOKELMA

Prophylaxis Yes ☐  
No ☒

Indication HYPERKALEMIA

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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Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 16:19:20

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERKALEMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication PROPAPENONE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication COMMUNITY-ACQUIRED  
PNEUMONIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication COMMUNITY-ACQUIRED  
PNEUMONIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication TORADOL

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 30

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 (26)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication COMMUNITY-ACQUIRED  
PNEUMONIA

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication FUROSEMIDE (LASIX)

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify EVERY 8 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

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

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	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)		19 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

Name of Medication XANAX

Prophylaxis Yes ☐  
No ☒

Indication PTSD

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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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US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 16:19:20

Generated On: 10 Jun 2021 08:10:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3542029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Feb 2021 22:29:51

Generated On: 10 Jun 2021 08:10:56

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3542029

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:10:56

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

US3542029

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:10:56

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 ☐

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 22 Mar 2021 19:21:53

Generated On: 10 Jun 2021 08:10:56

SAEID	USA-US084-2021-MRNA-1273-P301000006
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3



US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Mar 2021 19:21:53

Generated On: 10 Jun 2021 08:10:56

SAEID	USA-US084-2021-MRNA-1273-P301000006
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/FEB/2021 17:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Mar 2021 19:21:53

Generated On: 10 Jun 2021 08:10:56

SAEID	USA-US084-2021-MRNA-1273-P301000006
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/MAR/2021 07:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Mar 2021 19:21:53

Generated On: 10 Jun 2021 08:10:56

SAEID	USA-US084-2021-MRNA-1273-P301000006
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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/MAR/2021 15:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3542029 (Prod: George Washington University)

**US3542029**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:10:56**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:08:59
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'US3542029'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:24:23

US3542029

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:13

US3542029

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:24:24

US3542029

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[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 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:13



US3542029

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'SCRN'	System	20 Aug 2020 14:45:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:24:25

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '61'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'YEARS'	System	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '61'	System	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Female (F)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13
	(b) (4)	



US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'l'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13
	(b) (4)	

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:20:13

US3542029

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:10:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:13



US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Aug 2020'	System	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2020'	System	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Amendment 2 (2)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 14:45:37

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:37



US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:24:24

US3542029

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:10:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'l'	System	20 Aug 2020 14:45:47

US3542029

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:10:56

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 14:45:47

US3542029

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:10:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:20:36
	(b) (4)	

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
Data point term sent to Coder	System	21 Aug 2020 17:21:09
User entered 'Diabetes mellitus'	Taylor Ladson (b) (4)	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2010'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:06



US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:06
	(b) (4)	

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2010'	System	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2010'	System	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:06

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
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)	21 Aug 2020 17:22:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:19
Data point term sent to Coder	System	21 Aug 2020 17:22:10
User entered 'Hypertension'	Taylor Ladson (b) (4)	21 Aug 2020 17:21:20

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2010'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:20



US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2010'	System	21 Aug 2020 17:21:20

**US3542029**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:10:56**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2010'	System	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:20

US3542029

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:20



US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:19
Data point term sent to Coder	System	21 Aug 2020 17:22:12
User entered 'Depression'	Taylor Ladson (b) (4)	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:31
	(b) (4)	

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2015'	System	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2015'	System	21 Aug 2020 17:21:31



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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:31

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:23:17
Data point term sent to Coder	System	21 Aug 2020 17:22:14
User entered 'PTSD'	Taylor Ladson (b) (4)	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'UN UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:49

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:21:49



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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2015'	System	21 Aug 2020 17:21:49

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2015'	System	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:21:49

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 19:02:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 19:02:41
Data point term sent to Coder	System	25 Aug 2020 19:02:02
Coding entries removed.	Hannah Yellin (b) (4)	25 Aug 2020 19:01:30
User entered 'OSTEOARTHRITIS IN RIGHT KNEE' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:01:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:56:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:56:12
Data point term sent to Coder	System	21 Aug 2020 17:23:14
User entered 'Osteoarthritis in right knee'	Taylor Ladson (b) (4)	21 Aug 2020 17:22:30

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2017'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:30



US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:30
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2017'	System	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2017'	System	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:22:30

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 17:24:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 17:24:18
Data point term sent to Coder	System	21 Aug 2020 17:23:14
User entered 'Vitamin D deficiency'	Taylor Ladson (b) (4)	21 Aug 2020 17:22:46

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2019'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:46



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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:46

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2019'	System	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2019'	System	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:22:46

US3542029

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:22:46



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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:24:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:24:18
Data point term sent to Coder	System	21 Aug 2020 17:23:15
User entered 'Seasonal allergies'	Taylor Ladson (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2015'	System	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2015'	System	21 Aug 2020 17:23:01



US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	21 Aug 2020 17:23:01

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:38:52
Data point term sent to Coder	System	18 Sep 2020 16:37:38
User entered 'nephrolithiasis'	Taylor Ladson (b) (4)	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '0'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered empty.	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:37:37



US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2015'	System	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2015'	System	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	18 Sep 2020 16:37:37

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 20:48:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 20:48:28
Data point term sent to Coder	System	05 Oct 2020 20:47:16
User entered 'Post-menopausal'	Hannah Yellin (b) (4)	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User entered 'un UNK 2004'	(b) (4) Hannah Yellin (b) (4) (b) (4)	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	05 Oct 2020 20:46:50



US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:51:57
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2004'	System	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2004'	System	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	05 Oct 2020 20:46:50

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:02:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:02:06
Data point term sent to Coder	System	25 Feb 2021 20:45:53
User entered 'Paroxysmal atrial fibrillation'	Erika Faust (b) (4)	25 Feb 2021 20:45:49

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User entered 'UN UNK 2016'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:45:49



US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:45:49

**US3542029**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:45:49

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:45:49

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:45:49

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2016'	System	25 Feb 2021 20:45:49

**US3542029**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2016'	System	25 Feb 2021 20:45:49

**US3542029**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	25 Feb 2021 20:45:49

US3542029

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	25 Feb 2021 20:45:49



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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 17:46:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 17:46:54
Data point term sent to Coder	System	10 Mar 2021 17:45:55
User entered 'Hyperlipidemia'	Hannah Yellin (b) (4)	10 Mar 2021 17:45:39
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User entered 'un Jan 2020'	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 17:45:39
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 17:45:39

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 17:45:39

US3542029

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User entered empty.	(b) (4) Hannah Yellin (b) (4)	10 Mar 2021 17:45:39
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 18:40:17
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 17:45:39

US3542029

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'Jan 2020'	System	10 Mar 2021 17:45:39

**US3542029**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:10:56**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '2020'	System	10 Mar 2021 17:45:39



US3542029

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	10 Mar 2021 17:45:39

US3542029

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:10:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	10 Mar 2021 17:45:39

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10:32'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:24:32

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '20 Aug 2020 10:32'	System	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '168' cm	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:45:47

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '292' lb	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:45:47



US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
Amendment Manager: User entered '47.02639'	System	17 Sep 2020 00:15:47
User entered '47.0'	System	21 Aug 2020 17:24:32
DataPoint set to visible.	System	20 Aug 2020 14:45:47

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'kg/m2'	System	21 Aug 2020 17:24:32
DataPoint set to visible.	System	20 Aug 2020 14:45:47

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32
	(b) (4)	

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'bpm'	System	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32



US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'breaths/min'	System	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'mmHg'	System	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'mmHg'	System	21 Aug 2020 17:24:32

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47

US3542029

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47

US3542029

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:56
User entered 'No (N)' reason for change: New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:43
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:23
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:23
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	21 Aug 2020 17:24:47
	(b) (4)	



US3542029

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:46
User entered '20 Aug 2020' reason for change: New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:56
User entered empty; reason for change New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:43
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:23
User entered '20 Aug 2020' reason for change: New Information	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:12:23
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 17:24:47
	(b) (4)	

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User closed query 'Re-query: Please enter the condition on the medical history page.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 04:17:27
Query 'Re-query: Please enter the condition on the medical history page.' answered with 'Condition entered on medical history page' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	05 Oct 2020 20:47:05
User opened query 'Re-query: Please enter the condition on the medical history page.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:06:00
User closed query 'Re-Query: Thanks for the response however medical condition is still not updated on Medical History form. Please consider to update medical condition on medical history form.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:06:00
Query 'Re-Query: Thanks for the response however medical condition is still not updated on Medical History form. Please consider to update medical condition on medical history form.' answered with 'Thank you, PI has queried site monitor about re-evaluating this requirement given that menopause is a normal phase of life. This request is currently being escalated to data management.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:44:48
User opened query 'Re-Query: Thanks for the response however medical condition is still not updated on Medical History form. Please consider to update medical condition on medical history form.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 04:05:25
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 04:05:25

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

If No, what is the reason?

Audit	User	Time (GMT)
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'Thank you, will update medical conditions' (Site from DM).	Hannah Yellin (b) (4)	04 Sep 2020 20:04:10
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 08:03:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Taylor Ladson (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:18



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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2004'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:10:56

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:18

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 14:06:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Madhu Balachandran	29 Sep 2020 14:06:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	21 Aug 2020 17:25:56
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 14:06:11
	(b) (4)	
User entered 'Works from home' reason for change:	Madhu Balachandran	29 Sep 2020 14:06:11
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 17:25:56
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:56



US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:10:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:25:56

US3542029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	Elissa Malkin (b) (4)	20 Aug 2020 15:19:06



US3542029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	Elissa Malkin (b) (4)	20 Aug 2020 15:19:06

US3542029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[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 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered 'Clinic (Clinic)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 15:19:06

US3542029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'VISIT1'	System	20 Aug 2020 15:19:06

US3542029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:45:04

US3542029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:49:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:49:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 14:45:04
User entered '143743' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:45:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:24
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:45:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

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 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Hira Qadir (b) (4)	20 Aug 2020 15:42:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

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 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Hira Qadir (b) (4)	20 Aug 2020 15:42:34
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	20 Aug 2020 15:42:34

US3542029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	20 Aug 2020 15:42:34

US3542029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Hira Qadir (b) (4) (b) (4)	20 Aug 2020 15:42:34

US3542029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:10:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	29 Sep 2020 04:14:07
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	28 Sep 2020 19:35:17
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:42:41

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10:32'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '20 Aug 2020 10:32'	System	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '98.3' F reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:03:47
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 17:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:25
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:10
User entered empty; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:10
User entered '98.3' F	Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '91' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:03:47
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 17:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:25
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:10
User entered empty; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:10
User entered '91'	Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'bpm'	System	21 Aug 2020 17:29:25
User entered empty.	System	21 Aug 2020 17:29:10
User entered 'bpm'	System	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '16' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:03:47
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 17:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:25
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:10
User entered empty; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:10
User entered '16'	Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'breaths/min'	System	21 Aug 2020 17:29:25
User entered empty.	System	21 Aug 2020 17:29:10
User entered 'breaths/min'	System	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '139' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:03:47
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 17:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:25
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:10
User entered empty; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:10
User entered '139'	Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	21 Aug 2020 17:29:25
User entered empty.	System	21 Aug 2020 17:29:10
User entered 'mmHg'	System	21 Aug 2020 17:27:16

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '83' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:03:47
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 17:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:25
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 17:29:10
User entered empty; reason for change Data Entry Error	Taylor Ladson (b) (4)	21 Aug 2020 17:29:10
User entered '83'	Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	21 Aug 2020 17:29:25
User entered empty.	System	21 Aug 2020 17:29:10
User entered 'mmHg'	System	21 Aug 2020 17:27:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:10:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:27:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '11:45' reason for change: New Information	Taylor Ladson (b) (4)	21 Aug 2020 17:29:52
User entered '10:32'	Taylor Ladson (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '20 Aug 2020 11:45'	System	21 Aug 2020 17:29:52
User entered '20 Aug 2020 10:32'	System	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '98' F	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:28:39



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '83'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'bpm'	System	21 Aug 2020 17:28:39

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:24
User entered '24'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'breaths/min'	System	21 Aug 2020 17:28:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:24
User entered '126'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	21 Aug 2020 17:28:39



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	27 Aug 2020 15:36:24
User entered '72'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:28:39

US3542029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	21 Aug 2020 17:28:39

US3542029

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:46
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:13:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	DeEnna Wedding (b) (4)	11 Dec 2020 19:13:10
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	21 Aug 2020 17:30:18
	(b) (4)	

US3542029

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	13 Dec 2020 19:24:46
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	11 Dec 2020 19:13:10
	(b) (4)	
User entered empty; reason for change New Information	DeEnna Wedding (b) (4)	11 Dec 2020 19:13:10
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered '20 Aug 2020'	Taylor Ladson (b) (4)	21 Aug 2020 17:30:18
	(b) (4)	

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

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 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 15:19:53



US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '11:15'	(b) (4) Elissa Malkin (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '20 Aug 2020 11:15'	System	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Elissa Malkin (b) (4) (b) (4)	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'ONCE'	System	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 15:19:53

US3542029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:31:29

US3542029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:29



US3542029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10:54'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:29

US3542029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '20 Aug 2020 10:54'	System	21 Aug 2020 17:31:29

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '20 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10:56'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '20 Aug 2020 10:56'	System	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:55



US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered empty.	System	21 Aug 2020 17:31:55

US3542029

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:32:10

US3542029

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	21 Aug 2020 17:32:10

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:54:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '381c0513-86a1-4d5c-a525-350629b91189' User entered 'Yes (Y)'	System	20 Aug 2020 15:55:04
	System	20 Aug 2020 15:55:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:54:42', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '381c0513-86a1-4d5c-a525-350629b91189'	System	20 Aug 2020 15:55:04
User entered '98.0'	System	20 Aug 2020 15:55:04



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:54:48', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '381c0513-86a1-4d5c-a525-350629b91189'	System	20 Aug 2020 15:55:04
User entered 'No (N)'	System	20 Aug 2020 15:55:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '381c0513-86a1-4d5c-a525-350629b91189' User entered '20 Aug 2020 11:55'	System	20 Aug 2020 15:55:04
	System	20 Aug 2020 15:55:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 11:35'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 14:05'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:53:04', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8d097856-2d99-4e6d-9129-d25d28a9b414'	System	20 Aug 2020 23:53:22
User entered 'Yes (Y)'	System	20 Aug 2020 23:53:22

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:53:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8d097856-2d99-4e6d-9129-d25d28a9b414' User entered '98.3'	System	20 Aug 2020 23:53:22
	System	20 Aug 2020 23:53:22

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:53:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8d097856-2d99-4e6d-9129-d25d28a9b414'	System	20 Aug 2020 23:53:22
User entered 'No (N)'	System	20 Aug 2020 23:53:22



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:53:19', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8d097856-2d99-4e6d-9129-d25d28a9b414' User entered '20 Aug 2020 19:53'	System	20 Aug 2020 23:53:22
	System	20 Aug 2020 23:53:22

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 15:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 2'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:00:37', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '9e9d26c4-db60-4b34-9575-849f55cd57c9' User entered 'Yes (Y)'	System	21 Aug 2020 16:00:58
	System	21 Aug 2020 16:00:58

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:00:45', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '9e9d26c4-db60-4b34-9575-849f55cd57c9' User entered '98.4'	System	21 Aug 2020 16:00:58
	System	21 Aug 2020 16:00:58

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:00:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '9e9d26c4-db60-4b34-9575-849f55cd57c9'	System	21 Aug 2020 16:00:58
User entered 'No (N)'	System	21 Aug 2020 16:00:58

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:00:53', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '9e9d26c4-db60-4b34-9575-849f55cd57c9' User entered '21 Aug 2020 12:00'	System	21 Aug 2020 16:00:58
	System	21 Aug 2020 16:00:58



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 3'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:06:43', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6ac817b8-b62a-4af5-8a2d-f2e33a684480' User entered 'Yes (Y)'	System	22 Aug 2020 17:07:04
	System	22 Aug 2020 17:07:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:06:51', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6ac817b8-b62a-4af5-8a2d-f2e33a684480' User entered '98.6'	System	22 Aug 2020 17:07:04
	System	22 Aug 2020 17:07:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:06:55', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6ac817b8-b62a-4af5-8a2d-f2e33a684480' User entered 'No (N)'	System	22 Aug 2020 17:07:04
	System	22 Aug 2020 17:07:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6ac817b8-b62a-4af5-8a2d-f2e33a684480' User entered '22 Aug 2020 13:07'	System	22 Aug 2020 17:07:04
	System	22 Aug 2020 17:07:04

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:19:53



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 4'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:45:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2dc27f84-35fb-4ca3-8667-112c1b31ab21' User entered 'No (N)'	System	23 Aug 2020 17:45:42
	System	23 Aug 2020 17:45:42

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:45:36', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2dc27f84-35fb-4ca3-8667-112c1b31ab21'	System	23 Aug 2020 17:45:42
User entered 'No (N)'	System	23 Aug 2020 17:45:42

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:45:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2dc27f84-35fb-4ca3-8667-112c1b31ab21'	System	23 Aug 2020 17:45:42
User entered '23 Aug 2020 13:45'	System	23 Aug 2020 17:45:42

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 5'	System	20 Aug 2020 15:19:53



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56eee6a5-3f21-429d-9528-0b1eb8ca4bdc' User entered 'Yes (Y)'	System	24 Aug 2020 23:58:36
	System	24 Aug 2020 23:58:36

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56eee6a5-3f21-429d-9528-0b1eb8ca4bdc' User entered '98.6'	System	24 Aug 2020 23:58:36
	System	24 Aug 2020 23:58:36

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:28', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56eee6a5-3f21-429d-9528-0b1eb8ca4bdc' User entered 'No (N)'	System	24 Aug 2020 23:58:36
	System	24 Aug 2020 23:58:36

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56eee6a5-3f21-429d-9528-0b1eb8ca4bdc' User entered '24 Aug 2020 19:58'	System	24 Aug 2020 23:58:36
	System	24 Aug 2020 23:58:36

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 6'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:08', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '37ed9248-b319-4352-b978-2867b1237fc9'	System	25 Aug 2020 19:58:23
User entered 'No (N)'	System	25 Aug 2020 19:58:23



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '37ed9248-b319-4352-b978-2867b1237fc9'	System	25 Aug 2020 19:58:23
User entered 'No (N)'	System	25 Aug 2020 19:58:23

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:14', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '37ed9248-b319-4352-b978-2867b1237fc9' User entered '25 Aug 2020 15:58'	System	25 Aug 2020 19:58:23
	System	25 Aug 2020 19:58:23

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 7'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'fd4641f5-1cfb-4ed0-8ae2-c341ae112ef4'	System	26 Aug 2020 21:35:49
User entered 'No (N)'	System	26 Aug 2020 21:35:49

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'fd4641f5-1cfb-4ed0-8ae2-c341ae112ef4'	System	26 Aug 2020 21:35:49
User entered 'No (N)'	System	26 Aug 2020 21:35:49

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:45', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'fd4641f5-1cfb-4ed0-8ae2-c341ae112ef4'	System	26 Aug 2020 21:35:49
User entered '26 Aug 2020 17:35'	System	26 Aug 2020 21:35:49



US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '938c031c-06af-4aaf-9e61-cd88c884cb96'	System	20 Aug 2020 15:55:34
User entered 'None (1)'	System	20 Aug 2020 15:55:34

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:18', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '938c031c-06af-4aaf-9e61-cd88c884cb96'	System	20 Aug 2020 15:55:34
User entered 'No (N)'	System	20 Aug 2020 15:55:34

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:22', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '938c031c-06af-4aaf-9e61-cd88c884cb96'	System	20 Aug 2020 15:55:34
User entered 'No (N)'	System	20 Aug 2020 15:55:34

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '938c031c-06af-4aaf-9e61-cd88c884cb96'	System	20 Aug 2020 15:55:34
User entered 'None (1)'	System	20 Aug 2020 15:55:34

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '938c031c-06af-4aaf-9e61-cd88c884cb96'	System	20 Aug 2020 15:55:34
User entered '20 Aug 2020 11:55'	System	20 Aug 2020 15:55:34



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 11:35'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 14:05'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:51:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6230aa57-c128-400d-9365-468e9e068ef4'	System	20 Aug 2020 23:52:11
User entered 'None (1)'	System	20 Aug 2020 23:52:11

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:51:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6230aa57-c128-400d-9365-468e9e068ef4'	System	20 Aug 2020 23:52:11
User entered 'No (N)'	System	20 Aug 2020 23:52:11

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:51:59', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6230aa57-c128-400d-9365-468e9e068ef4'	System	20 Aug 2020 23:52:11
User entered 'No (N)'	System	20 Aug 2020 23:52:11

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:04', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6230aa57-c128-400d-9365-468e9e068ef4'	System	20 Aug 2020 23:52:11
User entered 'None (1)'	System	20 Aug 2020 23:52:11

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6230aa57-c128-400d-9365-468e9e068ef4' User entered '20 Aug 2020 19:52'	System	20 Aug 2020 23:52:11
	System	20 Aug 2020 23:52:11



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 15:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 2'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd626958e-fdbe-44ff-a7db-b85d2ec984a3'	System	21 Aug 2020 16:01:24
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 16:01:24

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd626958e-fdbe-44ff-a7db-b85d2ec984a3'	System	21 Aug 2020 16:01:24
User entered 'No (N)'	System	21 Aug 2020 16:01:24

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd626958e-fdbe-44ff-a7db-b85d2ec984a3'	System	21 Aug 2020 16:01:24
User entered 'No (N)'	System	21 Aug 2020 16:01:24

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd626958e-fdbe-44ff-a7db-b85d2ec984a3'	System	21 Aug 2020 16:01:24
User entered 'None (1)'	System	21 Aug 2020 16:01:24

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:22', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd626958e-fdbe-44ff-a7db-b85d2ec984a3' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 16:01:24
	System	21 Aug 2020 16:01:24



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 3'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7b10039a-7f94-438d-b4e1-ab2d20ae592e'	System	22 Aug 2020 17:07:28
User entered 'None (1)'	System	22 Aug 2020 17:07:28

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7b10039a-7f94-438d-b4e1-ab2d20ae592e' User entered 'No (N)'	System	22 Aug 2020 17:07:28
	System	22 Aug 2020 17:07:28

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7b10039a-7f94-438d-b4e1-ab2d20ae592e' User entered 'No (N)'	System	22 Aug 2020 17:07:28
	System	22 Aug 2020 17:07:28

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:19', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7b10039a-7f94-438d-b4e1-ab2d20ae592e'	System	22 Aug 2020 17:07:28
User entered 'None (1)'	System	22 Aug 2020 17:07:28

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7b10039a-7f94-438d-b4e1-ab2d20ae592e' User entered '22 Aug 2020 13:07'	System	22 Aug 2020 17:07:28
	System	22 Aug 2020 17:07:28



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 4'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:45:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7e5c14a4-328f-4c7b-abbd-e85993ce912f' User entered 'None (1)'	System	23 Aug 2020 17:46:10
	System	23 Aug 2020 17:46:10

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:45:51', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7e5c14a4-328f-4c7b-abbd-e85993ce912f' User entered 'No (N)'	System	23 Aug 2020 17:46:10
	System	23 Aug 2020 17:46:10

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7e5c14a4-328f-4c7b-abbd-e85993ce912f' User entered 'No (N)'	System	23 Aug 2020 17:46:10
	System	23 Aug 2020 17:46:10

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7e5c14a4-328f-4c7b-abbd-e85993ce912f' User entered 'None (1)'	System	23 Aug 2020 17:46:10
	System	23 Aug 2020 17:46:10

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:08', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7e5c14a4-328f-4c7b-abbd-e85993ce912f' User entered '23 Aug 2020 13:46'	System	23 Aug 2020 17:46:10
	System	23 Aug 2020 17:46:10



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 5'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:38', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2f2c8c2b-7b68-4112-a1c1-f61b092f4d1d' User entered 'None (1)'	System	24 Aug 2020 23:58:51
	System	24 Aug 2020 23:58:51

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2f2c8c2b-7b68-4112-a1c1-f61b092f4d1d' User entered 'No (N)'	System	24 Aug 2020 23:58:51
	System	24 Aug 2020 23:58:51

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:43', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2f2c8c2b-7b68-4112-a1c1-f61b092f4d1d' User entered 'No (N)'	System	24 Aug 2020 23:58:51
	System	24 Aug 2020 23:58:51

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2f2c8c2b-7b68-4112-a1c1-f61b092f4d1d' User entered 'None (1)'	System	24 Aug 2020 23:58:51
	System	24 Aug 2020 23:58:51

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:48', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2f2c8c2b-7b68-4112-a1c1-f61b092f4d1d' User entered '24 Aug 2020 19:58'	System	24 Aug 2020 23:58:51
	System	24 Aug 2020 23:58:51



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 6'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:18', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5355afcc-0792-4cee-91cf-f5474525da7d' User entered 'None (1)'	System	25 Aug 2020 19:58:35
	System	25 Aug 2020 19:58:35

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5355afcc-0792-4cee-91cf-f5474525da7d'	System	25 Aug 2020 19:58:35
User entered 'No (N)'	System	25 Aug 2020 19:58:35

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:24', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5355afcc-0792-4cee-91cf-f5474525da7d'	System	25 Aug 2020 19:58:35
User entered 'No (N)'	System	25 Aug 2020 19:58:35

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:27', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5355afcc-0792-4cee-91cf-f5474525da7d'	System	25 Aug 2020 19:58:35
User entered 'None (1)'	System	25 Aug 2020 19:58:35

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:30', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5355afcc-0792-4cee-91cf-f5474525da7d' User entered '25 Aug 2020 15:58'	System	25 Aug 2020 19:58:35
	System	25 Aug 2020 19:58:35



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 7'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '25373be0-35c7-4413-bcbf-bebd938fc694'	System	26 Aug 2020 21:36:02
User entered 'None (1)'	System	26 Aug 2020 21:36:02

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '25373be0-35c7-4413-bcbf-bebd938fc694' User entered 'No (N)'	System	26 Aug 2020 21:36:02
	System	26 Aug 2020 21:36:02

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '25373be0-35c7-4413-bcbf-bebd938fc694'	System	26 Aug 2020 21:36:02
User entered 'No (N)'	System	26 Aug 2020 21:36:02

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:35:58', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '25373be0-35c7-4413-bcbf-bebd938fc694'	System	26 Aug 2020 21:36:02
User entered 'None (1)'	System	26 Aug 2020 21:36:02

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '25373be0-35c7-4413-bcbf-bebd938fc694' User entered '26 Aug 2020 17:36'	System	26 Aug 2020 21:36:02
	System	26 Aug 2020 21:36:02



US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:55:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410' User entered 'None (0)'	System	20 Aug 2020 15:56:47
	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410'	System	20 Aug 2020 15:56:47
User entered 'No interference with activity (1)'	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410' User entered 'None (0)'	System	20 Aug 2020 15:56:47
	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410' User entered 'None (0)'	System	20 Aug 2020 15:56:47
	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:23', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410'	System	20 Aug 2020 15:56:47
User entered 'None (0)'	System	20 Aug 2020 15:56:47



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410'	System	20 Aug 2020 15:56:47
User entered 'None (0)'	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:32', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410'	System	20 Aug 2020 15:56:47
User entered 'No (N)'	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T11:56:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1e05a73f-4543-479f-9c2f-9049870a6410' User entered '20 Aug 2020 11:56'	System	20 Aug 2020 15:56:47
	System	20 Aug 2020 15:56:47

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 11:35'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 14:05'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:30', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:38', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'None (0)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:45', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90'	System	20 Aug 2020 23:52:53
User entered 'No (N)'	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-20T19:52:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '66fa0887-e0f8-4b1b-8181-929b25462a90' User entered '20 Aug 2020 19:52'	System	20 Aug 2020 23:52:53
	System	20 Aug 2020 23:52:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Aug 2020 15:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:19:53



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 2'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:28', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:32', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:38', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:50', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered 'None (0)'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103'	System	21 Aug 2020 16:02:07
User entered 'No (N)'	System	21 Aug 2020 16:02:07



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-21T12:01:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '432e1f37-bd97-44b6-abcf-8cd49e944103' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 16:02:07
	System	21 Aug 2020 16:02:07

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 3'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:30', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73'	System	22 Aug 2020 17:08:10
User entered 'None (0)'	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:36', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73' User entered 'None (0)'	System	22 Aug 2020 17:08:10
	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:44', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73' User entered 'None (0)'	System	22 Aug 2020 17:08:10
	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73'	System	22 Aug 2020 17:08:10
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:08:10



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:07:56', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73' User entered 'None (0)'	System	22 Aug 2020 17:08:10
	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:08:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73'	System	22 Aug 2020 17:08:10
User entered 'None (0)'	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:08:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73'	System	22 Aug 2020 17:08:10
User entered 'No (N)'	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-22T13:08:08', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bf275615-8da8-4b4c-a234-361f68e99f73'	System	22 Aug 2020 17:08:10
User entered '22 Aug 2020 13:08'	System	22 Aug 2020 17:08:10

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 4'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:13', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d' User entered 'None (0)'	System	23 Aug 2020 17:46:51
	System	23 Aug 2020 17:46:51



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:23', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d'	System	23 Aug 2020 17:46:51
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d'	System	23 Aug 2020 17:46:51
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d'	System	23 Aug 2020 17:46:51
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d' User entered 'None (0)'	System	23 Aug 2020 17:46:51
	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:42', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d' User entered 'None (0)'	System	23 Aug 2020 17:46:51
	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d'	System	23 Aug 2020 17:46:51
User entered 'No (N)'	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-23T13:46:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b39cf1ad-69f2-4a01-ba6e-4f3a5ff0e03d' User entered '23 Aug 2020 13:46'	System	23 Aug 2020 17:46:51
	System	23 Aug 2020 17:46:51

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:19:53



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 5'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:58:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc' User entered 'None (0)'	System	24 Aug 2020 23:59:22
	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc'	System	24 Aug 2020 23:59:22
User entered 'No interference with activity (1)'	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc'	System	24 Aug 2020 23:59:22
User entered 'No interference with activity (1)'	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc'	System	24 Aug 2020 23:59:22
User entered 'No interference with activity (1)'	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc' User entered 'None (0)'	System	24 Aug 2020 23:59:22
	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:14', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc' User entered 'None (0)'	System	24 Aug 2020 23:59:22
	System	24 Aug 2020 23:59:22



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:17', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc' User entered 'No (N)'	System	24 Aug 2020 23:59:22
	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-24T19:59:19', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a8462970-b1ba-4d4f-a990-e249e07600cc' User entered '24 Aug 2020 19:59'	System	24 Aug 2020 23:59:22
	System	24 Aug 2020 23:59:22

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 6'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'None (0)'	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:40', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:44', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:59:01



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017' User entered 'None (0)'	System	25 Aug 2020 19:59:01
	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'None (0)'	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017'	System	25 Aug 2020 19:59:01
User entered 'No (N)'	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-25T15:58:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '45e8bdf4-d60e-4a75-b218-a4239dc9f017' User entered '25 Aug 2020 15:58'	System	25 Aug 2020 19:59:01
	System	25 Aug 2020 19:59:01

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 7'	System	20 Aug 2020 15:19:53



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:18', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered 'None (0)'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:23', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084'	System	26 Aug 2020 21:36:28
User entered 'No (N)'	System	26 Aug 2020 21:36:28

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-08-26T17:36:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '01dae536-1a86-41f1-ac0e-9f05d7fbe084' User entered '26 Aug 2020 17:36'	System	26 Aug 2020 21:36:28
	System	26 Aug 2020 21:36:28



US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:19:53

US3542029

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	28 Aug 2020 15:57:11

US3542029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	05 Sep 2020 15:26:54
User entered '27 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	28 Aug 2020 15:57:11
	(b) (4)	

US3542029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	28 Aug 2020 15:57:11

US3542029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 15:26:54
User entered empty.	Taylor Ladson (b) (4) (b) (4)	28 Aug 2020 15:57:11

US3542029

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	05 Sep 2020 15:26:54
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	28 Aug 2020 15:56:34

US3542029

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	28 Aug 2020 15:56:34



US3542029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:40:56
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:34:58

US3542029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:40:56
User entered '03 Sep 2020'	Madhu Balachandran (b) (4)	08 Sep 2020 17:34:58

US3542029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	09 Sep 2020 01:40:56
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:34:58

US3542029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:40:56
User entered empty.	Madhu Balachandran (b) (4)	08 Sep 2020 17:34:58

US3542029

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	09 Sep 2020 01:40:56
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	08 Sep 2020 17:28:39

US3542029

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	08 Sep 2020 17:28:39

US3542029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	11 Sep 2020 17:00:12

US3542029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered '10 Sep 2020'	Madhu Balachandran (b) (4)	11 Sep 2020 17:00:12



US3542029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	11 Sep 2020 17:00:12

US3542029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 04:49:45
User entered empty.	Madhu Balachandran (b) (4)	11 Sep 2020 17:00:12

US3542029

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Sep 2020 04:49:45
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	11 Sep 2020 17:00:17

US3542029

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	11 Sep 2020 17:00:17

US3542029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:35:15

US3542029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:35:15

US3542029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[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 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered 'Clinic (Clinic)'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:15

US3542029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'VISIT2'	System	18 Sep 2020 16:35:15



US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '08:37'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '17 Sep 2020 08:37'	System	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '98.7' F	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered empty.	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:35:55



US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '91'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'bpm'	System	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '16'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'breaths/min'	System	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '138'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '81'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:55

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	18 Sep 2020 16:35:55



US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '10:14'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '17 Sep 2020 10:14'	System	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '98.5' F	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58



US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '93'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'bpm'	System	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '18'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'breaths/min'	System	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '137'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '83'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:58

US3542029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'mmHg'	System	18 Sep 2020 16:36:58



US3542029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:25

US3542029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:35:25

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4)	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:13:53
User entered empty.	(b) (4) Hira Qadir (b) (4)	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

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 06:16:13
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:13:53
User entered empty.	(b) (4) Hira Qadir (b) (4)	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	23 Sep 2020 15:13:53
User entered '09:44'	(b) (4) Hira Qadir (b) (4)	17 Sep 2020 13:52:27



US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '17 Sep 2020 09:44'	System	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hira Qadir (b) (4) (b) (4)	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'ONCE'	System	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:10:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 13:52:27

US3542029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:10

US3542029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:10

US3542029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '08:59'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:10

US3542029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '17 Sep 2020 08:59'	System	18 Sep 2020 16:36:10



US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered '17 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered '09:03'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered '17 Sep 2020 09:03'	System	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	23 Sep 2020 15:13:53
User entered empty.	Taylor Ladson (b) (4) (b) (4)	18 Sep 2020 16:36:26



US3542029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered empty.	System	18 Sep 2020 16:36:26

US3542029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:36:33

US3542029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'I'	System	18 Sep 2020 16:36:33

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:22:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'db84208e-4ac2-42b3-a70a-b945cc67ed79'	System	17 Sep 2020 14:22:53
User entered 'Yes (Y)'	System	17 Sep 2020 14:22:53

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:22:38', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'db84208e-4ac2-42b3-a70a-b945cc67ed79' User entered '98.5'	System	17 Sep 2020 14:22:53
	System	17 Sep 2020 14:22:53

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:22:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'db84208e-4ac2-42b3-a70a-b945cc67ed79'	System	17 Sep 2020 14:22:53
User entered 'No (N)'	System	17 Sep 2020 14:22:53

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:22:50', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'db84208e-4ac2-42b3-a70a-b945cc67ed79' User entered '17 Sep 2020 10:22'	System	17 Sep 2020 14:22:53
	System	17 Sep 2020 14:22:53



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 10:04'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 12:34'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a77ee633-992c-4fdd-90af-1c1daccb2277'	System	17 Sep 2020 20:01:20
User entered 'Yes (Y)'	System	17 Sep 2020 20:01:20

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a77ee633-992c-4fdd-90af-1c1daccb2277' User entered '98.2'	System	17 Sep 2020 20:01:20
	System	17 Sep 2020 20:01:20

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a77ee633-992c-4fdd-90af-1c1daccb2277'	System	17 Sep 2020 20:01:20
User entered 'No (N)'	System	17 Sep 2020 20:01:20

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:19', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a77ee633-992c-4fdd-90af-1c1daccb2277' User entered '17 Sep 2020 16:01'	System	17 Sep 2020 20:01:20
	System	17 Sep 2020 20:01:20

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 13:29'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 2'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3d315aa7-408d-4d54-87ec-014c8cd4c577'	System	18 Sep 2020 16:12:29
User entered 'Yes (Y)'	System	18 Sep 2020 16:12:29

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3d315aa7-408d-4d54-87ec-014c8cd4c577' User entered '97.0'	System	18 Sep 2020 16:12:29
	System	18 Sep 2020 16:12:29

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:24', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3d315aa7-408d-4d54-87ec-014c8cd4c577'	System	18 Sep 2020 16:12:29
User entered 'No (N)'	System	18 Sep 2020 16:12:29

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:27', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3d315aa7-408d-4d54-87ec-014c8cd4c577' User entered '18 Sep 2020 12:12'	System	18 Sep 2020 16:12:29
	System	18 Sep 2020 16:12:29

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 3'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f2684be7-df8e-4175-8a23-019b58fa4070' User entered 'Yes (Y)'	System	19 Sep 2020 20:56:16
	System	19 Sep 2020 20:56:16

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:07', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f2684be7-df8e-4175-8a23-019b58fa4070' User entered '98.4'	System	19 Sep 2020 20:56:16
	System	19 Sep 2020 20:56:16

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:10', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f2684be7-df8e-4175-8a23-019b58fa4070'	System	19 Sep 2020 20:56:16
User entered 'No (N)'	System	19 Sep 2020 20:56:16

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f2684be7-df8e-4175-8a23-019b58fa4070' User entered '19 Sep 2020 16:56'	System	19 Sep 2020 20:56:16
	System	19 Sep 2020 20:56:16

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 4'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1976c1aa-c515-4e30-96a5-2b105168456a' User entered 'Yes (Y)'	System	20 Sep 2020 20:20:22
	System	20 Sep 2020 20:20:22

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:14', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1976c1aa-c515-4e30-96a5-2b105168456a' User entered '98.5'	System	20 Sep 2020 20:20:22
	System	20 Sep 2020 20:20:22

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:17', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1976c1aa-c515-4e30-96a5-2b105168456a' User entered 'No (N)'	System	20 Sep 2020 20:20:22
	System	20 Sep 2020 20:20:22

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1976c1aa-c515-4e30-96a5-2b105168456a' User entered '20 Sep 2020 16:20'	System	20 Sep 2020 20:20:22
	System	20 Sep 2020 20:20:22

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 5'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a357de51-e6e1-4d5c-a008-5ff22a4f7836' User entered 'Yes (Y)'	System	21 Sep 2020 21:59:24
	System	21 Sep 2020 21:59:24



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a357de51-e6e1-4d5c-a008-5ff22a4f7836' User entered '97.8'	System	21 Sep 2020 21:59:24
	System	21 Sep 2020 21:59:24

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:17', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a357de51-e6e1-4d5c-a008-5ff22a4f7836'	System	21 Sep 2020 21:59:24
User entered 'No (N)'	System	21 Sep 2020 21:59:24

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a357de51-e6e1-4d5c-a008-5ff22a4f7836' User entered '21 Sep 2020 17:59'	System	21 Sep 2020 21:59:24
	System	21 Sep 2020 21:59:24

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 6'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:08:56', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '77e2eb78-8323-475f-adcd-1750595d77a6' User entered 'No (N)'	System	22 Sep 2020 16:09:07
	System	22 Sep 2020 16:09:07

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:08:59', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '77e2eb78-8323-475f-adcd-1750595d77a6'	System	22 Sep 2020 16:09:07
User entered 'No (N)'	System	22 Sep 2020 16:09:07



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '77e2eb78-8323-475f-adcd-1750595d77a6' User entered '22 Sep 2020 12:09'	System	22 Sep 2020 16:09:07
	System	22 Sep 2020 16:09:07

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 7'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:05:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2cacf6b0-c955-463a-a28b-202f251abf66' User entered 'No (N)'	System	23 Sep 2020 16:06:13
	System	23 Sep 2020 16:06:13

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:05:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2cacf6b0-c955-463a-a28b-202f251abf66'	System	23 Sep 2020 16:06:13
User entered 'No (N)'	System	23 Sep 2020 16:06:13

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:05:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2cacf6b0-c955-463a-a28b-202f251abf66'	System	23 Sep 2020 16:06:13
User entered '23 Sep 2020 12:05'	System	23 Sep 2020 16:06:13

US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:04', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a97b254f-6fe8-41ec-bfe2-d5b118be81c0'	System	17 Sep 2020 14:23:25
User entered 'None (1)'	System	17 Sep 2020 14:23:25

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:08', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a97b254f-6fe8-41ec-bfe2-d5b118be81c0'	System	17 Sep 2020 14:23:25
User entered 'No (N)'	System	17 Sep 2020 14:23:25

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a97b254f-6fe8-41ec-bfe2-d5b118be81c0'	System	17 Sep 2020 14:23:25
User entered 'No (N)'	System	17 Sep 2020 14:23:25

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a97b254f-6fe8-41ec-bfe2-d5b118be81c0'	System	17 Sep 2020 14:23:25
User entered 'None (1)'	System	17 Sep 2020 14:23:25

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:22', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a97b254f-6fe8-41ec-bfe2-d5b118be81c0' User entered '17 Sep 2020 10:23'	System	17 Sep 2020 14:23:25
	System	17 Sep 2020 14:23:25

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 10:04'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 12:34'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c'	System	17 Sep 2020 20:01:57
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 20:01:57

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c' User entered 'Yes (Y)'	System	17 Sep 2020 20:01:57
	System	17 Sep 2020 20:01:57

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:44', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c' User entered '12'	System	17 Sep 2020 20:01:57
	System	17 Sep 2020 20:01:57

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:50', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c' User entered 'No (N)'	System	17 Sep 2020 20:01:57
	System	17 Sep 2020 20:01:57

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:53', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c'	System	17 Sep 2020 20:01:57
User entered 'None (1)'	System	17 Sep 2020 20:01:57

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:01:55', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '46183a26-72f3-48ce-9999-90d3e9cdfc4c' User entered '17 Sep 2020 16:01'	System	17 Sep 2020 20:01:57
	System	17 Sep 2020 20:01:57



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 13:29'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 2'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3ed7857c-e098-4bb3-a29d-fe6f61313bb0'	System	18 Sep 2020 16:13:08
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 16:13:08

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3ed7857c-e098-4bb3-a29d-fe6f61313bb0' User entered 'No (N)'	System	18 Sep 2020 16:13:08
	System	18 Sep 2020 16:13:08

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:12:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3ed7857c-e098-4bb3-a29d-fe6f61313bb0' User entered 'No (N)'	System	18 Sep 2020 16:13:08
	System	18 Sep 2020 16:13:08

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3ed7857c-e098-4bb3-a29d-fe6f61313bb0'	System	18 Sep 2020 16:13:08
User entered 'None (1)'	System	18 Sep 2020 16:13:08

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3ed7857c-e098-4bb3-a29d-fe6f61313bb0' User entered '18 Sep 2020 12:13'	System	18 Sep 2020 16:13:08
	System	18 Sep 2020 16:13:08



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 3'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebc5-4a9b-9891-7497b97a48cf'	System	19 Sep 2020 20:57:13
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 20:57:13

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebe5-4a9b-9891-7497b97a48cf' User entered 'No (N)'	System	19 Sep 2020 20:57:13
	System	19 Sep 2020 20:57:13

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:56:36', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebc5-4a9b-9891-7497b97a48cf' User entered 'Yes (Y)'	System	19 Sep 2020 20:57:13
	System	19 Sep 2020 20:57:13

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:04', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebe5-4a9b-9891-7497b97a48cf' User entered '30'	System	19 Sep 2020 20:57:13
	System	19 Sep 2020 20:57:13

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:07', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebe5-4a9b-9891-7497b97a48cf' User entered 'None (1)'	System	19 Sep 2020 20:57:13
	System	19 Sep 2020 20:57:13



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '29075844-ebe5-4a9b-9891-7497b97a48cf' User entered '19 Sep 2020 16:57'	System	19 Sep 2020 20:57:13
	System	19 Sep 2020 20:57:13

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 4'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2d4a4cb8-e3e3-4e31-ad04-c68754af3e42'	System	20 Sep 2020 20:20:40
User entered 'None (1)'	System	20 Sep 2020 20:20:40

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2d4a4cb8-e3e3-4e31-ad04-c68754af3e42'	System	20 Sep 2020 20:20:40
User entered 'No (N)'	System	20 Sep 2020 20:20:40

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:32', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2d4a4cb8-e3e3-4e31-ad04-c68754af3e42'	System	20 Sep 2020 20:20:40
User entered 'No (N)'	System	20 Sep 2020 20:20:40

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2d4a4cb8-e3e3-4e31-ad04-c68754af3e42'	System	20 Sep 2020 20:20:40
User entered 'None (1)'	System	20 Sep 2020 20:20:40



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:37', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2d4a4cb8-e3e3-4e31-ad04-c68754af3e42'	System	20 Sep 2020 20:20:40
User entered '20 Sep 2020 16:20'	System	20 Sep 2020 20:20:40

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 5'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:23', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '252f466a-2ff9-4bfc-9774-dabdadf4cbc9'	System	21 Sep 2020 21:59:37
User entered 'None (1)'	System	21 Sep 2020 21:59:37

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:27', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '252f466a-2ff9-4bfc-9774-dabdadf4cbc9' User entered 'No (N)'	System	21 Sep 2020 21:59:37
	System	21 Sep 2020 21:59:37

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '252f466a-2ff9-4bfc-9774-dabdadf4cbc9' User entered 'No (N)'	System	21 Sep 2020 21:59:37
	System	21 Sep 2020 21:59:37

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '252f466a-2ff9-4bfc-9774-dabdadf4cbc9'	System	21 Sep 2020 21:59:37
User entered 'None (1)'	System	21 Sep 2020 21:59:37



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '252f466a-2ff9-4bfc-9774-dabdadf4cbc9' User entered '21 Sep 2020 17:59'	System	21 Sep 2020 21:59:37
	System	21 Sep 2020 21:59:37

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 6'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:07', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1a3a427c-a0e4-4f1c-abfb-e60eed1422c' User entered 'None (1)'	System	22 Sep 2020 16:09:31
	System	22 Sep 2020 16:09:31

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:18', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1a3a427c-a0e4-4f1c-abfb-e60eed1422c' User entered 'No (N)'	System	22 Sep 2020 16:09:31
	System	22 Sep 2020 16:09:31

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:22', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1a3a427c-a0e4-4f1c-abfb-e60eed1422c' User entered 'No (N)'	System	22 Sep 2020 16:09:31
	System	22 Sep 2020 16:09:31

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1a3a427c-a0e4-4f1c-abfb-e60eed1422c' User entered 'None (1)'	System	22 Sep 2020 16:09:31
	System	22 Sep 2020 16:09:31



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1a3a427c-a0e4-4f1c-abfb-e60eed1422c' User entered '22 Sep 2020 12:09'	System	22 Sep 2020 16:09:31
	System	22 Sep 2020 16:09:31

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 7'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:05:59', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd68c546c-dc96-46cf-a792-fef3d5d93e23'	System	23 Sep 2020 16:06:23
User entered 'None (1)'	System	23 Sep 2020 16:06:23

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd68c546c-dc96-46cf-a792-fef3d5d93e23'	System	23 Sep 2020 16:06:23
User entered 'No (N)'	System	23 Sep 2020 16:06:23

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd68c546c-dc96-46cf-a792-fef3d5d93e23'	System	23 Sep 2020 16:06:23
User entered 'No (N)'	System	23 Sep 2020 16:06:23

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:14', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd68c546c-dc96-46cf-a792-fef3d5d93e23'	System	23 Sep 2020 16:06:23
User entered 'None (1)'	System	23 Sep 2020 16:06:23



US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'd68c546c-dc96-46cf-a792-fef3d5d93e23' User entered '23 Sep 2020 12:06'	System	23 Sep 2020 16:06:23
	System	23 Sep 2020 16:06:23

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:37', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:40', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:43', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'None (0)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:50', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered 'No (N)'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T10:23:53', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '912a1bb3-2e18-4490-9b91-77aaf5182d47' User entered '17 Sep 2020 10:23'	System	17 Sep 2020 14:23:58
	System	17 Sep 2020 14:23:58

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 10:04'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 12:34'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2' User entered 'None (0)'	System	17 Sep 2020 20:02:39
	System	17 Sep 2020 20:02:39



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2'	System	17 Sep 2020 20:02:39
User entered 'Some interference with activity (2)'	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:09', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2'	System	17 Sep 2020 20:02:39
User entered 'Some interference with activity (2)'	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2'	System	17 Sep 2020 20:02:39
User entered 'Some interference with activity (2)'	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2' User entered 'None (0)'	System	17 Sep 2020 20:02:39
	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:19', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2'	System	17 Sep 2020 20:02:39
User entered 'No interference with activity (1)'	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2'	System	17 Sep 2020 20:02:39
User entered 'No (N)'	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-17T16:02:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'a7db3ed7-0bf7-4e8f-b8ba-49a3e3d161b2' User entered '17 Sep 2020 16:02'	System	17 Sep 2020 20:02:39
	System	17 Sep 2020 20:02:39

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '17 Sep 2020 13:29'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 2'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:10', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad' User entered 'None (0)'	System	18 Sep 2020 16:13:55
	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:17', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad'	System	18 Sep 2020 16:13:55
User entered 'Some interference with activity (2)'	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:22', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad'	System	18 Sep 2020 16:13:55
User entered 'Some interference with activity (2)'	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad' User entered 'Some interference with activity (2)'	System	18 Sep 2020 16:13:55
	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:28', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad' User entered 'None (0)'	System	18 Sep 2020 16:13:55
	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad'	System	18 Sep 2020 16:13:55
User entered 'No interference with activity (1)'	System	18 Sep 2020 16:13:55



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad' User entered 'No (N)'	System	18 Sep 2020 16:13:55
	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-18T12:13:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0abe918-cd91-4f78-a96b-9e4c9bf173ad' User entered '18 Sep 2020 12:13'	System	18 Sep 2020 16:13:55
	System	18 Sep 2020 16:13:55

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 3'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'None (0)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d'	System	19 Sep 2020 20:57:46
User entered 'No interference with activity (1)'	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:24', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'No interference with activity (1)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:28', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'No interference with activity (1)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'None (0)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'None (0)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:37', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered 'No (N)'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-19T16:57:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '14a052e6-b8b5-41c2-b895-4e661b8acd9d' User entered '19 Sep 2020 16:57'	System	19 Sep 2020 20:57:46
	System	19 Sep 2020 20:57:46

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 4'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:45', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'None (0)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:20:59', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered 'No (N)'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-20T16:21:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2ed1f4da-f8dd-4850-a8e6-38999f46f4a9' User entered '20 Sep 2020 16:21'	System	20 Sep 2020 20:21:03
	System	20 Sep 2020 20:21:03



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 5'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:44', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:49', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:51', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered 'None (0)'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T17:59:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79'	System	21 Sep 2020 22:00:07
User entered 'No (N)'	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-21T18:00:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7fd22bec-209e-4282-b9fc-b71f34d6de79' User entered '21 Sep 2020 18:00'	System	21 Sep 2020 22:00:07
	System	21 Sep 2020 22:00:07

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 6'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:36', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:40', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:44', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:50', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:52', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'None (0)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:09:56', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered 'No (N)'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-22T12:10:02', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'edaf30da-55a3-49b9-96fd-63f703ad86f3' User entered '22 Sep 2020 12:10'	System	22 Sep 2020 16:10:14
	System	22 Sep 2020 16:10:14

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:52:27



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	17 Sep 2020 13:52:27
User entered 'Day 7'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:23', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:27', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:32', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered 'None (0)'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:41', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a'	System	23 Sep 2020 16:06:49
User entered 'No (N)'	System	23 Sep 2020 16:06:49



US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-09-23T12:06:45', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '1f75f84f-3a40-41b8-acb7-e353ca59193a' User entered '23 Sep 2020 12:06'	System	23 Sep 2020 16:06:49
	System	23 Sep 2020 16:06:49

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:52:27

US3542029

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:10:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:52:27

US3542029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 15:25:30

US3542029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered '24 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 15:25:30

US3542029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 15:25:30

US3542029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	29 Sep 2020 04:14:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Sep 2020 15:25:30

US3542029

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Sep 2020 15:25:37



US3542029

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	25 Sep 2020 15:25:37

US3542029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:38
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	02 Oct 2020 19:58:00

US3542029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:05
Signature has been broken.	(b) (4), (b) (6)	17 Nov 2020 14:56:03
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 14:56:03
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:38
User entered '1 Oct 2020'	Madhu Balachandran (b) (4)	02 Oct 2020 19:58:00

US3542029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:38
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	02 Oct 2020 19:58:00

US3542029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	03 Oct 2020 15:26:38
User entered empty.	Madhu Balachandran (b) (4)	02 Oct 2020 19:58:00

US3542029

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:26:38
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	02 Oct 2020 19:58:24

US3542029

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	02 Oct 2020 19:58:24

US3542029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:19:29
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	09 Oct 2020 17:56:58



US3542029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:19:29
User entered '8 Oct 2020'	Madhu Balachandran (b) (4)	09 Oct 2020 17:56:58

US3542029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Oct 2020 02:19:29
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	09 Oct 2020 17:56:58

US3542029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4) (b) (4)	14 Oct 2020 02:19:29
User entered empty.	Madhu Balachandran (b) (4)	09 Oct 2020 17:56:58

US3542029

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:19:29
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	09 Oct 2020 17:57:00

US3542029

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	09 Oct 2020 17:57:00

US3542029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:29:32
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:17:49

US3542029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '15 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:17:49
	(b) (4)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

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 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered 'Clinic (Clinic)'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:17:49
	(b) (4)	



**US3542029**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:10:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered 'VISIT3'	System	16 Oct 2020 17:17:49

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '15 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30
	(b) (4)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '08:28'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered '15 Oct 2020 08:28'	System	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
	(b) (4)	
User entered '98.0' F	DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30
	(b) (4)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered 'Oral (Oral)'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30
	(b) (4)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30



US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '87'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered 'bpm'	System	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '17'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered 'breaths/min'	System	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '163'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered 'mmHg'	System	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered '94'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:18:30

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered 'mmHg'	System	16 Oct 2020 17:18:30



US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31

US3542029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31

US3542029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:18:41

US3542029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '15 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:18:41

US3542029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:18:57

US3542029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '15 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:18:57

US3542029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User signature succeeded.	David Diemert (u) (4) (b) (4)	21 Oct 2020 18:29:32
User entered '08:49'	DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:18:57

US3542029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:31
User entered '15 Oct 2020 08:49'	System	16 Oct 2020 17:18:57



US3542029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	21 Oct 2020 18:29:32
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:19:11
	(b) (4)	

US3542029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'I'	System	16 Oct 2020 17:19:11

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 64'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-20T00:57:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0c91a9f-ba77-4583-b02f-90039d80375f' User entered 'No (N)'	System	20 Oct 2020 04:57:27
	System	20 Oct 2020 04:57:27

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-20T00:57:18', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0c91a9f-ba77-4583-b02f-90039d80375f' User entered 'No (N)'	System	20 Oct 2020 04:57:27
	System	20 Oct 2020 04:57:27

**US3542029**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-20T00:57:24', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e0c91a9f-ba77-4583-b02f-90039d80375f' User entered '20 Oct 2020 00:57:24'	System	20 Oct 2020 04:57:27
	System	20 Oct 2020 04:57:27

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 15:19:53



US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 71'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-27T02:36:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bd18f408-4e7a-4953-a455-dbd625c143b0'	System	27 Oct 2020 06:36:45
User entered 'No (N)'	System	27 Oct 2020 06:36:45

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-27T02:36:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bd18f408-4e7a-4953-a455-dbd625c143b0'	System	27 Oct 2020 06:36:45
User entered 'No (N)'	System	27 Oct 2020 06:36:45

**US3542029**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-10-27T02:36:42', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'bd18f408-4e7a-4953-a455-dbd625c143b0' User entered '27 Oct 2020 02:36:42'	System	27 Oct 2020 06:36:45
	System	27 Oct 2020 06:36:45

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 78'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-05T12:01:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '38b5df35-5776-45cd-81bd-1c34fac2b56b' User entered 'No (N)'	System	05 Nov 2020 17:04:13
	System	05 Nov 2020 17:04:13



US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-05T12:01:51', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '38b5df35-5776-45cd-81bd-1c34fac2b56b'	System	05 Nov 2020 17:04:13
User entered 'No (N)'	System	05 Nov 2020 17:04:13

**US3542029**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-05T12:01:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '38b5df35-5776-45cd-81bd-1c34fac2b56b' User entered '05 Nov 2020 12:01:57'	System	05 Nov 2020 17:04:13
	System	05 Nov 2020 17:04:13

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered 'Day 92'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-17T19:10:54', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f6299b25-c691-4f8c-8421-2e4c0585351b' User entered 'No (N)'	System	18 Nov 2020 00:11:09
	System	18 Nov 2020 00:11:09

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-17T19:10:58', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f6299b25-c691-4f8c-8421-2e4c0585351b'	System	18 Nov 2020 00:11:09
User entered 'No (N)'	System	18 Nov 2020 00:11:09

**US3542029**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-17T19:11:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f6299b25-c691-4f8c-8421-2e4c0585351b' User entered '17 Nov 2020 19:11:05'	System	18 Nov 2020 00:11:09
	System	18 Nov 2020 00:11:09



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 15:19:53

US3542029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:29:25
Data entry locked.	System	20 Aug 2020 15:19:53
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 15:19:53

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-28T10:59:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f21d5a3-fca4-462a-b384-27652c1d5492'	System	28 Nov 2020 16:00:24
User entered 'No (N)'	System	28 Nov 2020 16:00:24

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-28T11:00:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f21d5a3-fca4-462a-b384-27652c1d5492'	System	28 Nov 2020 16:00:24
User entered 'No (N)'	System	28 Nov 2020 16:00:24



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-11-28T11:00:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f21d5a3-fca4-462a-b384-27652c1d5492' User entered '28 Nov 2020 11:00:21'	System	28 Nov 2020 16:00:24
	System	28 Nov 2020 16:00:24

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-05T21:37:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e4faffc4-12d8-49fe-b026-b7ab1bdfbb5a' User entered 'No (N)'	System	06 Dec 2020 02:37:19

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-05T21:37:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e4faffc4-12d8-49fe-b026-b7ab1bdfbb5a' User entered 'No (N)'	System	06 Dec 2020 02:37:19

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-05T21:37:16', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e4faffc4-12d8-49fe-b026-b7ab1bdfbb5a' User entered '05 Dec 2020 21:37:16'	System	06 Dec 2020 02:37:19
	System	06 Dec 2020 02:37:19

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:39:08

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:49:30
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'The corresponding MAAE is recorded on the AE eCRF page - this refers to Sinusitis that began 12/7/20' (Site from DM).	Erika Faust (b) (4) (b) (4)	08 Mar 2021 14:55:06
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:19:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:11:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7'	System	12 Dec 2020 15:12:45
User entered 'Yes (Y)'	System	12 Dec 2020 15:12:45

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:11:51', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7' User entered 'No (N)'	System	12 Dec 2020 15:12:45
	System	12 Dec 2020 15:12:45

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:11:58', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7'	System	12 Dec 2020 15:12:45
User entered 'No (N)'	System	12 Dec 2020 15:12:45

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:12:10', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7'	System	12 Dec 2020 15:12:45
User entered 'Yes (Y)'	System	12 Dec 2020 15:12:45

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Please 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:12:26', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7'	System	12 Dec 2020 15:12:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 15:12:45

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-12T10:12:33', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6c4b0f72-7f36-47bc-b18f-e2d6890942a7' User entered '12 Dec 2020 10:12:33'	System	12 Dec 2020 15:12:45
	System	12 Dec 2020 15:12:45



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-20T00:36:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8cca0ae1-ab42-41b2-b4bf-6ee127c67e02'	System	20 Dec 2020 05:36:43
User entered 'No (N)'	System	20 Dec 2020 05:36:43

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-20T00:36:34', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8cca0ae1-ab42-41b2-b4bf-6ee127c67e02'	System	20 Dec 2020 05:36:43
User entered 'No (N)'	System	20 Dec 2020 05:36:43

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-20T00:36:40', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '8cca0ae1-ab42-41b2-b4bf-6ee127c67e02'	System	20 Dec 2020 05:36:43
User entered '20 Dec 2020 00:36:40'	System	20 Dec 2020 05:36:43

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:39:08

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-27T22:11:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e10b1d91-0515-4624-9620-2d9349b17129' User entered 'No (N)'	System	28 Dec 2020 03:12:11
	System	28 Dec 2020 03:12:11

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-27T22:12:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e10b1d91-0515-4624-9620-2d9349b17129' User entered 'No (N)'	System	28 Dec 2020 03:12:11

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2020-12-27T22:12:08', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'e10b1d91-0515-4624-9620-2d9349b17129'	System	28 Dec 2020 03:12:11
User entered '27 Dec 2020 22:12:08'	System	28 Dec 2020 03:12:11

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-02T00:01:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f66f2fbe-b8f1-4a88-bc49-1404c43420b0' User entered 'No (N)'	System	02 Jan 2021 05:01:43
	System	02 Jan 2021 05:01:43



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-02T00:01:25', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f66f2fbe-b8f1-4a88-bc49-1404c43420b0'	System	02 Jan 2021 05:01:43
User entered 'No (N)'	System	02 Jan 2021 05:01:43

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-02T00:01:29', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f66f2fbe-b8f1-4a88-bc49-1404c43420b0' User entered '02 Jan 2021 00:01:29'	System	02 Jan 2021 05:01:43
	System	02 Jan 2021 05:01:43

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-11T07:39:06', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f4dc218-c955-432b-b2ac-b126c8b78805'	System	11 Jan 2021 12:41:45
User entered 'No (N)'	System	11 Jan 2021 12:41:45

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-11T07:39:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f4dc218-c955-432b-b2ac-b126c8b78805'	System	11 Jan 2021 12:41:45
User entered 'No (N)'	System	11 Jan 2021 12:41:45

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-11T07:39:15', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '5f4dc218-c955-432b-b2ac-b126c8b78805' User entered '11 Jan 2021 07:39:15'	System	11 Jan 2021 12:41:45
	System	11 Jan 2021 12:41:45



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-16T00:02:31', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '0e5f62bb-0b88-4df9-94dc-7ec87d2bd80c' User entered 'No (N)'	System	16 Jan 2021 05:04:09
	System	16 Jan 2021 05:04:09

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-16T00:02:35', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '0e5f62bb-0b88-4df9-94dc-7ec87d2bd80c' User entered 'No (N)'	System	16 Jan 2021 05:04:09

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-16T00:02:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '0e5f62bb-0b88-4df9-94dc-7ec87d2bd80c' User entered '16 Jan 2021 00:02:39'	System	16 Jan 2021 05:04:09
	System	16 Jan 2021 05:04:09

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-23T00:01:57', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7991cc8a-83b2-4735-b860-9f246ccd01ae' User entered 'No (N)'	System	23 Jan 2021 05:03:04
	System	23 Jan 2021 05:03:04

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-23T00:02:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7991cc8a-83b2-4735-b860-9f246ccd01ae' User entered 'No (N)'	System	23 Jan 2021 05:03:04

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-23T00:02:05', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '7991cc8a-83b2-4735-b860-9f246ccd01ae' User entered '23 Jan 2021 00:02:05'	System	23 Jan 2021 05:03:04
	System	23 Jan 2021 05:03:04

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-30T08:28:40', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '532cf13f-2b7c-4ace-be32-15f74198c10d' User entered 'No (N)'	System	30 Jan 2021 13:29:25



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-30T08:29:12', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '532cf13f-2b7c-4ace-be32-15f74198c10d' User entered 'No (N)'	System	30 Jan 2021 13:29:25

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-01-30T08:29:21', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '532cf13f-2b7c-4ace-be32-15f74198c10d' User entered '30 Jan 2021 08:29:21'	System	30 Jan 2021 13:29:25
	System	30 Jan 2021 13:29:25

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-06T00:57:48', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6feaeb93-9e9a-41f5-a184-4d743ff85cb5' User entered 'No (N)'	System	06 Feb 2021 05:58:00

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-06T00:57:55', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6feaeb93-9e9a-41f5-a184-4d743ff85cb5'	System	06 Feb 2021 05:58:00
User entered 'No (N)'	System	06 Feb 2021 05:58:00

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-06T00:57:58', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6feab93-9e9a-41f5-a184-4d743ff85cb5'	System	06 Feb 2021 05:58:00
User entered '06 Feb 2021 00:57:58'	System	06 Feb 2021 05:58:00



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:39:08

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-13T00:01:47', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2b981d34-af19-4c23-988d-190c20ff0d46'	System	13 Feb 2021 05:03:30
User entered 'No (N)'	System	13 Feb 2021 05:03:30

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-13T00:01:56', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2b981d34-af19-4c23-988d-190c20ff0d46'	System	13 Feb 2021 05:03:30
User entered 'No (N)'	System	13 Feb 2021 05:03:30

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-13T00:02:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '2b981d34-af19-4c23-988d-190c20ff0d46'	System	13 Feb 2021 05:03:30
User entered '13 Feb 2021 00:02:01'	System	13 Feb 2021 05:03:30

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:18:39', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514'	System	20 Feb 2021 05:19:33
User entered 'Yes (Y)'	System	20 Feb 2021 05:19:33

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:18:46', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514' User entered 'No (N)'	System	20 Feb 2021 05:19:33

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:18:53', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514' User entered 'No (N)'	System	20 Feb 2021 05:19:33
	System	20 Feb 2021 05:19:33

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:19:01', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514'	System	20 Feb 2021 05:19:33
User entered 'Yes (Y)'	System	20 Feb 2021 05:19:33

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Please 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:19:11', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514'	System	20 Feb 2021 05:19:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Feb 2021 05:19:33

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-02-20T00:19:20', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'ecbf9c32-0461-4086-b970-f10da48ac514' User entered '20 Feb 2021 00:19:20'	System	20 Feb 2021 05:19:33
	System	20 Feb 2021 05:19:33

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-01T08:20:38-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f3aa0a40-9d4e-4e00-b206-3d3a617a3028'	System	01 Mar 2021 13:20:51
User entered 'No (N)'	System	01 Mar 2021 13:20:51

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-01T08:20:41-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f3aa0a40-9d4e-4e00-b206-3d3a617a3028'	System	01 Mar 2021 13:20:51
User entered 'No (N)'	System	01 Mar 2021 13:20:51

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-01T08:20:46-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f3aa0a40-9d4e-4e00-b206-3d3a617a3028'	System	01 Mar 2021 13:20:51
User entered '01 Mar 2021 08:20:46'	System	01 Mar 2021 13:20:51

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-06T00:14:07-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '4a257668-b4b7-4f56-af64-80c13a9f5f37'	System	06 Mar 2021 05:14:19
User entered 'No (N)'	System	06 Mar 2021 05:14:19

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-06T00:14:11-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '4a257668-b4b7-4f56-af64-80c13a9f5f37'	System	06 Mar 2021 05:14:19
User entered 'No (N)'	System	06 Mar 2021 05:14:19

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-06T00:14:17-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '4a257668-b4b7-4f56-af64-80c13a9f5f37'	System	06 Mar 2021 05:14:19
User entered '06 Mar 2021 00:14:17'	System	06 Mar 2021 05:14:19

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-13T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b83658b7-b3f3-434f-a36c-b7abd99e40fc'	System	13 Mar 2021 05:04:17
User entered 'No (N)'	System	13 Mar 2021 05:04:17

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-13T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b83658b7-b3f3-434f-a36c-b7abd99e40fc'	System	13 Mar 2021 05:04:17
User entered 'No (N)'	System	13 Mar 2021 05:04:17



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-13T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b83658b7-b3f3-434f-a36c-b7abd99e40fc'	System	13 Mar 2021 05:04:17
User entered '13 Mar 2021 00:02:40'	System	13 Mar 2021 05:04:17

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-20T21:03:39-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '72f7c844-f3e0-4776-80d5-d6998fde4c8c'	System	21 Mar 2021 01:09:32
User entered 'No (N)'	System	21 Mar 2021 01:09:32

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-20T21:04:08-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '72f7c844-f3e0-4776-80d5-d6998fde4c8c'	System	21 Mar 2021 01:09:32
User entered 'No (N)'	System	21 Mar 2021 01:09:32

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-20T21:04:13-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '72f7c844-f3e0-4776-80d5-d6998fde4c8c'	System	21 Mar 2021 01:09:32
User entered '20 Mar 2021 21:04:13'	System	21 Mar 2021 01:09:32

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:39:08

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-28T06:27:42-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3c3de3c1-bf9a-4061-9ae7-80aa7fd67265'	System	28 Mar 2021 10:27:53
User entered 'No (N)'	System	28 Mar 2021 10:27:53

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-28T06:27:46-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3c3de3c1-bf9a-4061-9ae7-80aa7fd67265'	System	28 Mar 2021 10:27:53
User entered 'No (N)'	System	28 Mar 2021 10:27:53

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-28T06:27:52-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '3c3de3c1-bf9a-4061-9ae7-80aa7fd67265'	System	28 Mar 2021 10:27:53
User entered '28 Mar 2021 06:27:52'	System	28 Mar 2021 10:27:53

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-03T21:40:22-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b5aff69d-7b53-4de1-ba25-d871d0f2a6e9'	System	04 Apr 2021 01:40:30
User entered 'No (N)'	System	04 Apr 2021 01:40:30

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-03T21:40:25-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b5aff69d-7b53-4de1-ba25-d871d0f2a6e9'	System	04 Apr 2021 01:40:30
User entered 'No (N)'	System	04 Apr 2021 01:40:30

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-03T21:40:28-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'b5aff69d-7b53-4de1-ba25-d871d0f2a6e9'	System	04 Apr 2021 01:40:30
User entered '03 Apr 2021 21:40:28'	System	04 Apr 2021 01:40:30

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:39:08

US3542029

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-12T12:00:46-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56af48d3-677d-4398-9c82-1c55af287a7e' User entered 'No (N)'	System	12 Apr 2021 16:03:13
	System	12 Apr 2021 16:03:13

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-12T12:00:47-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56af48d3-677d-4398-9c82-1c55af287a7e'	System	12 Apr 2021 16:03:13
User entered 'No (N)'	System	12 Apr 2021 16:03:13



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-12T12:00:51-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '56af48d3-677d-4398-9c82-1c55af287a7e'	System	12 Apr 2021 16:03:13
User entered '12 Apr 2021 12:00:51'	System	12 Apr 2021 16:03:13

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:39:08

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-17T00:36:02-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'cf51178b-15f8-4223-8674-d1ff28a25a0f' User entered 'No (N)'	System	17 Apr 2021 04:36:14
	System	17 Apr 2021 04:36:14

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-17T00:36:04-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'cf51178b-15f8-4223-8674-d1ff28a25a0f' User entered 'No (N)'	System	17 Apr 2021 04:36:14

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-17T00:36:09-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'cf51178b-15f8-4223-8674-d1ff28a25a0f' User entered '17 Apr 2021 00:36:09'	System	17 Apr 2021 04:36:14
	System	17 Apr 2021 04:36:14

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-24T00:36:33-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f7b094a7-8028-4060-8803-723e32b777a9' User entered 'No (N)'	System	24 Apr 2021 04:36:48
	System	24 Apr 2021 04:36:48

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-24T00:36:36-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f7b094a7-8028-4060-8803-723e32b777a9'	System	24 Apr 2021 04:36:48
User entered 'No (N)'	System	24 Apr 2021 04:36:48

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-04-24T00:36:42-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f7b094a7-8028-4060-8803-723e32b777a9'	System	24 Apr 2021 04:36:48
User entered '24 Apr 2021 00:36:42'	System	24 Apr 2021 04:36:48

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:39:08



US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

[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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-05-01T02:41:26-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f9fa0fd3-01f9-4962-9104-4f2f20f80142'	System	01 May 2021 06:41:37
User entered 'No (N)'	System	01 May 2021 06:41:37

US3542029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:10:56

Have you been exposed to someone with 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 (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-05-01T02:41:28-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f9fa0fd3-01f9-4962-9104-4f2f20f80142'	System	01 May 2021 06:41:37
User entered 'No (N)'	System	01 May 2021 06:41:37

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-05-01T02:41:33-04:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: 'f9fa0fd3-01f9-4962-9104-4f2f20f80142'	System	01 May 2021 06:41:37
User entered '01 May 2021 02:41:33'	System	01 May 2021 06:41:37

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:39:08



**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:39:08

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:39:08



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:39:08

**US3542029**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:10:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:39:08
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:39:08

US3542029

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:10:56**

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 10:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-01T08:21:01-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6a898fda-c077-4835-ae49-7d877c9ba299'	System	01 Mar 2021 13:21:09
User entered 'No (N)'	System	01 Mar 2021 13:21:09

US3542029

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:10:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0C37576-732C-4294-84E0-49E1C8BE6D75)', Time: '2021-03-01T08:21:07-05:00', User OID: 'PatientReportedOutcome (US3542029)', ODM File OID: '6a898fda-c077-4835-ae49-7d877c9ba299'	System	01 Mar 2021 13:21:09
User entered '01 Mar 2021 08:21:07'	System	01 Mar 2021 13:21:09

US3542029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:45:17
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Nov 2020 16:14:03

US3542029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:45:17
User entered '12 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Nov 2020 16:14:03



US3542029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:45:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Nov 2020 16:14:03

US3542029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 21:45:17
User entered empty.	(b) (4) Erika Faust (b) (4)	12 Nov 2020 16:14:03
	(b) (4)	

US3542029

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User signature succeeded.	David Diemert (u) (4)	12 Nov 2020 21:45:17
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	12 Nov 2020 16:14:07

US3542029

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:16:13
User entered 'l'	System	12 Nov 2020 16:14:07

**US3542029**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:10:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 17:13:30

US3542029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered '17 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 17:13:30

**US3542029**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:10:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 17:13:30

US3542029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered empty.	(b) (4) Erika Faust (b) (4)	18 Dec 2020 17:13:30



US3542029

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	27 Dec 2020 22:57:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 17:13:34

US3542029

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered 'l'	System	18 Dec 2020 17:13:34

US3542029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:03:30

US3542029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User entered '14 Jan 2021'	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:03:30

US3542029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:03:30

US3542029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	15 Jan 2021 19:03:30

US3542029

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:03:34

US3542029

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered 'l'	System	15 Jan 2021 19:03:34



**US3542029**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:10:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:23:49

**US3542029**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:10:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:51
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:23:49

**US3542029**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:10:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 17:23:49

US3542029

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:51
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 17:23:49

US3542029

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 16:59:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:23:54

US3542029

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered 'l'	System	12 Feb 2021 17:23:54

US3542029

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:50:52

US3542029

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '18 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:50:52



US3542029

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:50:52

US3542029

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered 'VISIT4'	System	19 Mar 2021 16:50:52

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered empty.	System	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32



US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered empty.	System	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered empty.	System	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered empty.	System	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	31 Mar 2021 21:12:50
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	31 Mar 2021 14:20:32



US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered empty.	System	31 Mar 2021 14:20:32

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15

US3542029

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:10:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15

US3542029

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:06

US3542029

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:10:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:06

US3542029

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:18

US3542029

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '18 Mar 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:18

US3542029

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '13:40'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:18



US3542029

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered '18 Mar 2021 13:40'	System	19 Mar 2021 16:51:18

US3542029

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:51:23

US3542029

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:49:15
User entered 'I'	System	19 Mar 2021 16:51:23

US3542029

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Apr 2021 20:06:22
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Apr 2021 15:52:46

US3542029

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Apr 2021 20:06:22
User entered '15 Apr 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Apr 2021 15:52:46

US3542029

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Apr 2021 20:06:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erika Faust (b) (4)	16 Apr 2021 15:52:46

US3542029

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:10:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Apr 2021 20:06:22
User entered 'Left voicemails at 11:47, 14:22, 15:37'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Apr 2021 15:52:46

US3542029

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:10:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	16 Apr 2021 20:06:22
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	16 Apr 2021 15:53:01



**US3542029**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:10:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:53:01

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 17:26:32

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:26:32

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[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 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:26:32

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:10:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 17:26:32

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:26:50

**US3542029**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:10:56**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:37
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:57:54

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 17:26:50



US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:37
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:57:54

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 17:26:50

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	25 Jan 2021 17:26:50

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	25 Jan 2021 17:26:50

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	25 Jan 2021 17:26:50

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 17:26:50

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:10:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	25 Jan 2021 17:26:50

**US3542029**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:10:56**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered empty.	System	25 Jan 2021 17:26:50



US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 17:27:06

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 17:27:06

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '08:35'	(b) (4), (b) (6)	25 Jan 2021 17:27:06

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:10:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '25 Jan 2021 08:35'	System	25 Jan 2021 17:27:06

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 17:27:15

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 17:27:15

US3542029

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:10:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:39
User entered '08:38'	(b) (4), (b) (6)	25 Jan 2021 17:27:15

**US3542029**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:10:56**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:44:47
User entered '25 Jan 2021 08:38'	System	25 Jan 2021 17:27:15



US3542029

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:10:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:27:08
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:45:59

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 14:00:51
Data point term sent to Coder	System	29 Sep 2020 13:59:36
Coding entries removed.	Madhu Balachandran	29 Sep 2020 13:58:55
Signature has been broken.	(b) (4)	29 Sep 2020 13:58:55
User entered 'Urinary Tract Infection' reason for change: Data Entry Error	Madhu Balachandran	29 Sep 2020 13:58:55
User signature succeeded.	(b) (4)	05 Sep 2020 15:26:44
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: Back pain - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 17:47:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 17:47:41
Data point term sent to Coder	System	04 Sep 2020 17:47:19
User entered 'Back pain'	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 13:40:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	21 Oct 2020 13:40:03
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'No (N)'	(b) (4)	
	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '02 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47



US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
User entered empty.	System	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 13:58:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Madhu Balachandran	29 Sep 2020 13:58:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
	(b) (4)	
User entered 'Yes (Y)'	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 13:58:55
	(b) (4)	
User entered '12 Sep 2020' reason for change: Data Entry Error	Madhu Balachandran	29 Sep 2020 13:58:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47
	(b) (4)	

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
User entered empty.	System	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47



US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47



US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'None (NONE)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 13:57:29
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
	(b) (4)	
User entered '0'	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47
	(b) (4)	

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered 'l'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

US3542029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:35:53
Signature has been broken.	(b) (4)	
	Madhu Balachandran	29 Sep 2020 13:58:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Madhu Balachandran	29 Sep 2020 13:58:55
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Hannah Yellin (b) (4)	04 Sep 2020 17:46:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:44
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:46:47

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
User entered '0'	System	04 Sep 2020 17:46:47

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52
User entered '1'	System	21 Oct 2020 13:40:03
User entered '0'	System	04 Sep 2020 17:46:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 01:13:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 01:13:39
Data point term sent to Coder	System	16 Oct 2020 17:22:22
User entered 'chills'	DeEnna Wedding (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52



US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '12 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:21:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
User entered empty.	System	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '14 Oct 2020'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
User entered empty.	System	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'No (N)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Not Related (NOT RELATED)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Not Related (NOT RELATED)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'None (NONE)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52



US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Oct 2020 17:22:04
User entered '1' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	16 Oct 2020 17:22:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Oct 2020 17:21:52
User entered '0'	DeEnna Wedding (b) (4)	16 Oct 2020 17:21:52
	(b) (4)	

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered '0'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User entered empty.	(b) (4) DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:21:52

US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
User entered '0'	System	16 Oct 2020 17:21:52

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54
User entered '0'	System	16 Oct 2020 17:21:52



US3542029

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:09:54

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User closed query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:40:22
Query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Participant had typical symptoms of sinusitis. Was treated with oral antibiotics by her PCP; COVID-19 test performed by PCP was negative. Illness Visit therefore not judged to be necessary, by PI.' (Site from DM).	David Diemert (b) (4)	04 Feb 2021 22:34:29
User opened query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:27:52
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 17:31:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 17:31:56
Data point term sent to Coder	System	15 Dec 2020 17:31:24

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Sinusitis'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '07 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 17:30:27



**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
User entered empty.	System	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	15 Jan 2021 19:05:28
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Taylor Ladson (b) (4)	15 Jan 2021 19:05:28
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	15 Jan 2021 19:05:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Jan 2021 19:05:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Jan 2021 19:05:28
Signature has been broken.	Taylor Ladson (b) (4) (b) (4)	15 Jan 2021 19:05:28
User entered '17 Dec 2020' reason for change: New Information	Taylor Ladson (b) (4) (b) (4)	15 Jan 2021 19:05:28
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
User entered empty.	System	15 Dec 2020 17:30:27

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

US3542029

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'l'	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:30:27



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	15 Jan 2021 19:05:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Taylor Ladson (b) (4)	15 Jan 2021 19:05:52
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
User entered '0'	System	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01
User entered 'I'	System	15 Dec 2020 17:30:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 01:33:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 01:33:04
Data point term sent to Coder	System	24 Feb 2021 18:44:06
User entered 'Atrial fibrillation (worsening)'	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 18:47:25
User entered '18 Feb 2021' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 18:43:19
User entered '18 Feb ' (non-conformant).	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User entered empty.	System	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'No (N)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 21:52:22
DataPoint Un-verified.	(b) (4) David Diemert (b) (4)	17 Mar 2021 21:50:06
Signature has been broken.	(b) (4) David Diemert (b) (4)	17 Mar 2021 21:50:06
User entered '19 Feb 2021' reason for change: Per Query Resolution	(b) (4) David Diemert (b) (4)	17 Mar 2021 21:50:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:07
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:47:38
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Feb 2021 18:47:38
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:47:38
User entered '18 Feb 2021' reason for change: Per Query Resolution	Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:47:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:47:25
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 18:47:25
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User entered empty.	System	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'No (N)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	



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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:43:19
User entered empty.	System	24 Feb 2021 18:43:19
	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	24 Feb 2021 18:49:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Feb 2021 18:43:19
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Resolution date of AE changed. Overlaps now with ConMed of propafenone.' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:12:22
DataPoint Verified.	David Diemert (b) (4) (b) (4)	17 Mar 2021 21:50:33
User signature succeeded.	(b) (4), (b) (6)	17 Mar 2021 07:08:22
User entered '1' reason for change: Per Query Resolution User entered '0'	(b) (4), (b) (6) David Diemert (b) (4) (b) (4) Caroline Thoreson (b) (4) (b) (4) Caroline Thoreson (b) (4) (b) (4)	03 Mar 2021 16:40:37 25 Feb 2021 20:43:07 24 Feb 2021 18:49:04 24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Feb 2021 18:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 18:47:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Caroline Thoreson (b) (4)	24 Feb 2021 18:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 18:43:19
User entered empty.	Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:43:19

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:10:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User entered '0'	System	24 Feb 2021 18:47:25



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06
User entered 'I'	System	24 Feb 2021 18:43:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:06

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:40:37
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:21
User entered	System	25 Feb 2021 22:24:16
'USA-US084-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 22:24:16

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hyperkalemia, LLT: Hyperkalemia - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 11:07:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 11:07:48
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure, unspecified - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 14:32:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 14:32:35
Data point term sent to Coder	System	19 Mar 2021 20:30:44
User closed query 'CDM Coding, please split the term (HYPERKALEMIA DUE TO ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY) into two separate records, as 'HYPERKALEMIA' and 'ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	19 Mar 2021 20:30:06
Query 'CDM Coding, please split the term (HYPERKALEMIA DUE TO ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY) into two separate records, as 'HYPERKALEMIA' and 'ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'I will keep this AE term as is but add a second one of AKI even though the hyperkalemia is really just a manifestation of the AKI. ' (Site from System).	David Diemert (b) (4)	19 Mar 2021 20:30:06

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding, please split the term (HYPERKALEMIA DUE TO ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY) into two separate records, as 'HYPERKALEMIA' and 'ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	19 Mar 2021 03:07:59
Data point term sent to Coder DataPoint Un-verified.	David Diemert (b) (4) System	11 Mar 2021 17:55:57 11 Mar 2021 17:37:37
Coding entries removed.	David Diemert (b) (4) (b) (4)	11 Mar 2021 17:36:47 11 Mar 2021 17:36:47
Signature has been broken.	David Diemert (b) (4) (b) (4)	11 Mar 2021 17:36:47 11 Mar 2021 17:36:47
User entered 'HYPERKALEMIA due to Acute Kidney Injury of Unknown Etiology' reason for change: Per Query Resolution DataPoint Verified.	David Diemert (b) (4) (b) (4), (b) (6)	11 Mar 2021 17:36:47 03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hyperkalaemia, LLT: Hyperkalemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:16:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:16:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hyperkalaemia, LLT: Hyperkalemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:00:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:00:07
Data point term sent to Coder User entered 'Hyperkalemia'	System Caroline Thoreson (b) (4) (b) (4)	24 Feb 2021 18:59:38 24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '18 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

US3542029

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:10:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '20 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:10:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28



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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'I'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '18 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '22 Feb 2021'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28



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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'l'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28



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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:26
User closed query 'PV Query: Please assess if right flank pain, which the subject presented to the ED on 2/15 as per discharge summary, meets reporting criteria as a AE/SAE' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:30:48
User closed query 'PV Query: Please provide date of repeat blood culture, which was negative per DS.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:30:43
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
Query 'PV Query: Please provide date of repeat blood culture, which was negative per DS.' answered with 'Added to narrative.' (Site from Safety).	David Diemert (b) (4)	19 Mar 2021 20:29:06
Signature has been broken.	David Diemert (b) (4)	19 Mar 2021 20:29:00
User entered 'PT WITH UNDERLYING IDDM, HYPERTENSION, HYPERLIPIDEMIA, PAROXYSMAL ATRIAL FIBRILLATION, AND NEPHROLITHIASIS WAS BROUGHT TO GWU ED ON 18-FEB-2021 AFTER BEING FOUND UNCONSCIOUS AT HOME BY DAUGHTER. SHE WAS FOUND TO HAVE HYPERKALEMIA, ACUTE KIDNEY INJURY, HYPERGLYCEMIA, COMMUNITY ACQUIRED PNEUMONIA AND ATRIAL FIBRILLATION (WITH RVR). COVID-19 PCR (DONE 18FEB2021) WAS NEGATIVE. SHE WAS ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. SHE WAS GIVEN LOKELMA AND CALCIUM GLUCONATE. Blood cultures performed on 21FEB2021 were negative. PT WAS DISCHARGED FROM HOSPITAL ON 22-FEB-2021. REASON FOR ADMISSION WAS HYPERKALEMIA LIKELY DUE TO ACUTE KIDNEY INJURY OF UNCERTAIN ETIOLOGY.' reason for change: Per Query Resolution	David Diemert (b) (4)	19 Mar 2021 20:29:00

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please assess if right flank pain, which the subject presented to the ED on 2/15 as per discharge summary, meets reporting criteria as a AE/SAE' answered with 'It doesn't. It fits into AE of abdominal pain that has already been reported.' (Site from Safety).	David Diemert (b) (4)	19 Mar 2021 20:21:40
User opened query 'PV Query: Please assess if right flank pain, which the subject presented to the ED on 2/15 as per discharge summary, meets reporting criteria as a AE/SAE' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 03:52:19
User opened query 'PV Query: Please provide date of repeat blood culture, which was negative per DS.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 03:51:42
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:50:04
User closed query 'PV Query: It was reported the subject was discharged on 24Feb2021 however, discharge date has been entered as 22Feb2021. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:50:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:49:54
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:49:38
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)	12 Mar 2021 15:49:01
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Narrative has been updated.' (Site from Safety).	David Diemert (b) (4)	11 Mar 2021 17:47:19
User entered 'PT with underlying IDDM, hypertension, hyperlipidemia, paroxysmal atrial fibrillation, and nephrolithiasis was brought TO GWU ED ON 18-FEB-2021 AFTER being found unconscious at home by daughter. SHE WAS FOUND TO HAVE HYPERKALEMIA, ACUTE KIDNEY INJURY, hyperglycemia, COMMUNITY ACQUIRED PNEUMONIA AND ATRIAL FIBRILLATION (WITH RVR). COVID-19 PCR (DONE 18FEB2021) WAS NEGATIVE. SHE WAS ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. SHE WAS GIVEN LOKELMA AND CALCIUM GLUCONATE. PT WAS DISCHARGED FROM HOSPITAL ON 22-FEB-2021. Reason for admission was hyperkalemia likely due to acute kidney injury of uncertain etiology.' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Mar 2021 17:47:06
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 'Testing was done on admission and was negative. Added to narrative.' (Site from Safety).	David Diemert (b) (4)	11 Mar 2021 17:41:36
User entered 'PT PRESENTED TO GWU ED ON 18-FEB-2021 AFTER EXPERIENCING SYNCOPAL EPISODE. SHE WAS FOUND TO HAVE HYPERKALEMIA, ACUTE KIDNEY INJURY, COMMUNITY ACQUIRED PNEUMONIA AND ATRIAL FIBRILLATION (WITH RVR). COVID-19 PCR (done 18FEB2021) was negative. SHE WAS ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. SHE WAS GIVEN LOKELMA AND CALCIUM GLUCONATE. PT WAS DISCHARGED FROM HOSPITAL ON 22-FEB-2021.' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Mar 2021 17:39:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT PRESENTED TO GWU ED ON 18-FEB-2021 AFTER EXPERIENCING SYNCOPAL EPISODE. SHE WAS FOUND TO HAVE HYPERKALEMIA, acute kidney injury, COMMUNITY ACQUIRED PNEUMONIA AND ATRIAL FIBRILLATION (WITH RVR). SHE WAS ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. SHE WAS GIVEN LOKELMA AND CALCIUM GLUCONATE. PT WAS DISCHARGED FROM HOSPITAL ON 22-FEB-2021.' reason for change: Per Query Resolution	David Diemert (b) (4)	11 Mar 2021 17:37:24
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Faxed as requested.' (Site from Safety).	David Diemert (b) (4)	11 Mar 2021 17:27:49
Query 'PV Query: It was reported the subject was discharged on 24Feb2021 however, discharge date has been entered as 22Feb2021. Please reconcile.' answered with 'Corrected.' (Site from Safety).	David Diemert (b) (4)	11 Mar 2021 17:27:39
DataPoint Un-verified.	David Diemert (b) (4)	11 Mar 2021 17:27:29
Signature has been broken.	David Diemert (b) (4)	11 Mar 2021 17:27:29
User entered 'PT PRESENTED TO GWU ED ON 18-FEB-2021 AFTER EXPERIENCING SYNCOPAL EPISODE. SHE WAS FOUND TO HAVE HYPERKALEMIA, COMMUNITY ACQUIRED PNEUMONIA AND ATRIAL FIBRILLATION (WITH RVR). SHE WAS ADMITTED FOR FURTHER WORK-UP AND MANAGEMENT. SHE WAS GIVEN LOKELMA AND CALCIUM GLUCONATE. PT WAS DISCHARGED FROM HOSPITAL ON 22-FEB-2021.' reason for change: Data Entry Error	David Diemert (b) (4)	11 Mar 2021 17:27:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Faxed as requested.' (Site from Safety).	David Diemert (b) (4)	11 Mar 2021 17:25:30
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:25:15
User opened query 'PV Query: It was reported the subject was discharged on 24Feb2021 however, discharge date has been entered as 22Feb2021. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:25:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:24:37
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:24:25
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)	04 Mar 2021 16:24:16
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User signature succeeded.	David Diemert (b) (4)	25 Feb 2021 20:43:07



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt presented to GWU ED on 18-FEB-2021 after experiencing syncopal episode. She was found to have hyperkalemia, community acquired pneumonia and atrial fibrillation (with RVR). She was admitted for further work-up and management. She was given Lokelma and calcium gluconate. Pt was discharged from hospital on 24-FEB-2021.'	Caroline Thoreson (b) (4)	24 Feb 2021 18:59:28

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 18:59:28

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	24 Feb 2021 18:59:28

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 18:59:28

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Community acquired pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:06:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:06:01
Data point term sent to Coder	System	25 Feb 2021 20:49:59
User entered 'Community acquired pneumonia'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Yes (Y)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User entered empty.	System	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
DataPoint Un-verified.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:49:50
Signature has been broken.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:49:50
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:49:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
User entered '28 Feb 2021' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User entered empty.	System	25 Feb 2021 20:49:37



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37



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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Applicable (NOT APPLICABLE)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'l'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
DataPoint Un-verified.	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	19 Mar 2021 16:49:50
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erika Faust (b) (4)	25 Feb 2021 20:49:37
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:49:37

US3542029

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User entered '0'	System	25 Feb 2021 20:49:37

US3542029

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:10:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20
User entered 'I'	System	25 Feb 2021 20:49:37

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:20



US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Blood gas and acid base analyses, PT: Blood lactic acid increased, LLT: Blood lactic acid increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:28:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:28:01
Data point term sent to Coder	System	25 Feb 2021 20:52:01
User entered 'elevated lactic acid'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Yes (Y)'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User entered empty.	System	25 Feb 2021 20:51:16



US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '19 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User entered empty.	System	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16



US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Applicable (NOT APPLICABLE)'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 21:52:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	17 Mar 2021 21:43:35
Signature has been broken.	David Diemert (b) (4)	17 Mar 2021 21:43:35
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4)	17 Mar 2021 21:43:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User signature succeeded.	System	17 Mar 2021 21:42:46
DataPoint Verified.	David Diemert (b) (4)	11 Mar 2021 17:55:57
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:40:37
	Erika Faust (b) (4)	25 Feb 2021 20:51:16
	(b) (4)	

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:12:43
User signature succeeded.	David Diemert (b) (4)	17 Mar 2021 21:52:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Corrected.' (Site from DM).	(b) (4) David Diemert (b) (4)	17 Mar 2021 21:43:42
DataPoint Un-verified.	David Diemert (b) (4)	17 Mar 2021 21:42:46
Signature has been broken.	(b) (4) David Diemert (b) (4)	17 Mar 2021 21:42:46
User entered '0' reason for change: Per Query Resolution	David Diemert (b) (4)	17 Mar 2021 21:42:46
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:08:44
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '1'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16



**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User entered '0'	System	25 Feb 2021 20:51:16

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11
User entered 'I'	System	25 Feb 2021 20:51:16

US3542029

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:11

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:54:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:54:01
Data point term sent to Coder	System	25 Feb 2021 20:53:02
User entered 'abdominal pain'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:52:07



US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User entered empty.	System	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '22 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User entered empty.	System	25 Feb 2021 20:52:07



**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07



US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Not Applicable (NOT APPLICABLE)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:52:07



**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'l'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

US3542029

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:10:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User signature succeeded.	David Diemert (b) (4)	11 Mar 2021 17:55:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:40:37
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User entered '0'	System	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13
User entered 'I'	System	25 Feb 2021 20:52:07

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:13



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 20:36:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 20:36:46
Data point term sent to Coder	System	19 Mar 2021 20:35:51
User entered 'Acute kidney injury'	David Diemert (b) (4)	19 Mar 2021 20:35:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Yes (Y)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '18 Feb 2021'	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User entered empty.	System	19 Mar 2021 20:35:17



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '19 Feb 2021' reason for change: Data Entry Error	System	19 Mar 2021 20:42:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	David Diemert (b) (4)	19 Mar 2021 20:42:11
User entered '29 Feb 2021' (non-conformant).	(b) (4)	
	System	19 Mar 2021 20:35:17
	David Diemert (b) (4)	19 Mar 2021 20:35:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User entered empty.	System	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17



US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Not Related (NOT RELATED)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Not Related (NOT RELATED)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'l'	David Diemert (b) (4)	19 Mar 2021 20:35:17

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	David Diemert (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	David Diemert (b) (4)	19 Mar 2021 20:35:17

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17



US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User entered '0'	System	19 Mar 2021 20:35:17

US3542029

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:10:56

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24
User entered 'I'	System	19 Mar 2021 20:35:17

**US3542029**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:56:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:10:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:41:38
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:32:52

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:08:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:08:45
Data point term sent to Coder Coding entries removed.	System Hannah Yellin (b) (4)	25 Aug 2020 19:07:21 25 Aug 2020 19:06:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:35:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:35:19
Data point term sent to Coder User entered 'Meloxicam'	System Taylor Ladson (b) (4)	21 Aug 2020 17:34:36 21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Osteoarthritis' reason for change: Data Entry Error	(b) (4)	25 Aug 2020 19:06:40
User entered 'OA'	Hannah Yellin (b) (4)	25 Aug 2020 19:06:40
	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:33:54
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '15'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'UN UNK 2019'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:33:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Aug 2020 17:34:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:34:30
User entered 'No (N)' reason for change: New Information	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:34:30
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:33:54
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:33:54

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:33:54

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 17:33:54

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:33:54

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:37:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:37:19
Data point term sent to Coder	System	21 Aug 2020 17:36:40
User entered 'Vitamin D'	Taylor Ladson (b) (4)	21 Aug 2020 17:35:45



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Vitamin D deficiency'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '1000'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	25 Aug 2020 19:07:01
User entered 'Other (OTHER)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:35:45
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty; reason for change Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	25 Aug 2020 19:07:01
	(b) (4)	
User entered 'U'	Taylor Ladson (b) (4)	21 Aug 2020 17:35:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'UN UNK 2020'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:35:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:35:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:35:45



**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:35:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:09:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:09:37
Data point term sent to Coder Coding entries removed.	System Hannah Yellin (b) (4)	25 Aug 2020 19:08:26 25 Aug 2020 19:07:35
User entered 'LORATADINE' reason for change: Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:07:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:39:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:39:25
Data point term sent to Coder User entered 'Loratidine'	System Taylor Ladson (b) (4)	21 Aug 2020 17:37:44 21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Seasonal allergies'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:36:53



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:36:53

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:36:53

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:36:53

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VILAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: VIIBRYD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:39:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:39:26
Data point term sent to Coder	System	21 Aug 2020 17:38:45
User entered 'Viibryd'	Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Depression'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '30'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45
	(b) (4)	

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2017'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:37:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:37:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 17:37:45

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:37:45

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:41:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:41:16
Data point term sent to Coder	System	21 Aug 2020 17:39:47
User entered 'Lisinopril'	Taylor Ladson (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Hypertension'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '40'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 12:59:12
User closed query 'Please confirm. Per source end date 18Feb2021.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:58:44
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
Query 'Please confirm. Per source end date 18Feb2021.' answered with 'Updated' (Site from CRA).	Hannah Yellin (b) (4)	10 Mar 2021 17:47:01
DataPoint Un-verified.	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
Signature has been broken.	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User opened query 'Please confirm. Per source end date 18Feb2021.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:43:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 12:59:00
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
User entered '18 Feb 2021' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:46:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 17:39:05
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:05

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
User entered '1'	System	21 Aug 2020 17:39:05

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
User entered 'I'	System	21 Aug 2020 17:39:05

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:38
User entered '804 (804)'	System	21 Aug 2020 17:39:05

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 17:51:54
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 Mar 2021 17:51:54
Data point term sent to Coder Coding entries removed.	System Hannah Yellin (b) (4) (b) (4)	10 Mar 2021 17:51:01 10 Mar 2021 17:50:11
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 01:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 01:19:46
Data point term sent to Coder Coding entries removed.	System DeEnna Wedding (b) (4) (b) (4)	16 Oct 2020 17:23:25 16 Oct 2020 17:23:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:41:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:41:17
Data point term sent to Coder User entered 'Atorvastatin'	System Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:47 21 Aug 2020 17:39:46

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
Signature has been broken.	(b) (4)	
	DeEnna Wedding (b) (4)	16 Oct 2020 17:23:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	DeEnna Wedding (b) (4)	16 Oct 2020 17:23:16
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:39:46
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
User entered 'Hyperlipidemia' reason for change:	(b) (4)	
New Information	Hannah Yellin (b) (4)	10 Mar 2021 17:50:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. (Site from DM).	DeEnna Wedding (b) (4)	16 Oct 2020 17:23:33
' answered with 'indication changed' (Site from DM).	(b) (4)	
Signature has been broken.	DeEnna Wedding (b) (4)	16 Oct 2020 17:23:16
	(b) (4)	
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	DeEnna Wedding (b) (4)	16 Oct 2020 17:23:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	05 Oct 2020 09:46:27
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered 'Hypertension'	Taylor Ladson (b) (4)	21 Aug 2020 17:39:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '10'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'once daily (QD)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN Jan 2020' reason for change: Per Query Resolution	System	21 Aug 2020 17:39:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Taylor Ladson (b) (4)	21 Aug 2020 17:39:58
User entered 'un Jan 2-2-' (non-conformant).	(b) (4)	
	System	21 Aug 2020 17:39:46
	Taylor Ladson (b) (4)	21 Aug 2020 17:39:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 12:58:08
User closed query 'Please confirm. Per source end date is 18Feb2021.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 12:57:39
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
Query 'Please confirm. Per source end date is 18Feb2021.' answered with 'Updated' (Site from CRA).	Hannah Yellin (b) (4)	10 Mar 2021 17:47:24
DataPoint Un-verified.	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
Signature has been broken.	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
User entered 'No (N)' reason for change: New Information	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User opened query 'Please confirm. Per source end date is 18Feb2021.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:44:15
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 12:58:18
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
User entered '18 Feb 2021' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:47:18
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	21 Aug 2020 17:39:46
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:39:46

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User entered 'I'	System	21 Aug 2020 17:39:46

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User entered 'I'	System	21 Aug 2020 17:39:46



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:28
User entered '804 (804)'	System	21 Aug 2020 17:39:46

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:43:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:43:22
Data point term sent to Coder	System	21 Aug 2020 17:41:49
User entered 'Metformin'	Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Diabetes mellitus'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '1000'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'twice daily (BID)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2019'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:41:03



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 17:41:03

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 17:41:03

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:41:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:13:36
Data point term sent to Coder	System	21 Aug 2020 17:42:57
User entered 'Humalog'	Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Diabetes mellitus'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '15'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	25 Aug 2020 19:08:57
User entered 'Other (OTHER)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:42:08
	(b) (4)	



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty; reason for change Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	25 Aug 2020 19:08:57
	(b) (4)	
User entered 'U'	Taylor Ladson (b) (4)	21 Aug 2020 17:42:08
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'three times daily (TID)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'UN UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:42:08

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Aug 2020 17:42:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 17:42:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:42:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:45:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:45:21
Data point term sent to Coder	System	21 Aug 2020 17:43:58
User entered 'Tresiba'	Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Diabetes Mellitus'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:33:45
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' answered with 'Dose units corrected.' (Site from DM).	David Diemert (b) (4) (b) (4)	07 Oct 2020 20:28:47
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:46:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:36:24
User entered '30'	Taylor Ladson (b) (4) (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	07 Oct 2020 20:27:41
User entered 'Other (OTHER)' reason for change:	(b) (4)	
New Information	David Diemert (b) (4)	07 Oct 2020 20:27:41
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'mg (mg)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:29:32
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	07 Oct 2020 20:27:41
User entered 'units' reason for change: New Information	(b) (4)	
	David Diemert (b) (4)	07 Oct 2020 20:27:41
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Hannah Yellin (b) (4)	25 Aug 2020 19:10:33
User entered 'once daily (QD)'	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Every night' reason for change: Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	25 Aug 2020 19:10:33
User entered empty.	(b) (4)	
	Taylor Ladson (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'un UNK 2015'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered '0'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered empty.	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:36:24
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	21 Aug 2020 17:43:20

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:10:33
User entered 'l'	System	21 Aug 2020 17:43:20

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:10:33
User entered '1'	System	21 Aug 2020 17:43:20

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:10:33
User entered '804 (804)'	System	21 Aug 2020 17:43:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
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)	25 Mar 2021 11:15:25
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 Mar 2021 11:15:25
Data point term sent to Coder	System	23 Mar 2021 20:11:16
Coding entries removed.	David Diemert (b) (4) (b) (4)	23 Mar 2021 20:11:06
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:26:54
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)	04 Sep 2020 17:49:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:49:43
Data point term sent to Coder	System	04 Sep 2020 17:48:25
User entered 'Advil'	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User signature succeeded.	David Diemert (b) (4)	25 Mar 2021 16:06:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	25 Mar 2021 07:38:42
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	David Diemert (b) (4)	23 Mar 2021 20:11:31
' answered with 'Updated. Back pain was secondary to UTI.' (Site from DM).	(b) (4)	
DataPoint Un-verified.	David Diemert (b) (4)	23 Mar 2021 20:11:06
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	23 Mar 2021 20:11:06
User entered 'Urinary tract infection' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	David Diemert (b) (4)	23 Mar 2021 20:11:06
' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:53:16
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'Back pain'	(b) (4)	
	Hannah Yellin (b) (4)	04 Sep 2020 17:47:39
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered '400'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
User entered 'as needed (PRN)' reason for change:	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
	(b) (4)	
User entered 'once daily (QD)'	Hannah Yellin (b) (4)	04 Sep 2020 17:47:39
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered '02 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
	(b) (4)	
User entered 'Yes (Y)'	Hannah Yellin (b) (4)	04 Sep 2020 17:47:39
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
User entered '12 Sep 2020' reason for change: New Information	Hannah Yellin (b) (4)	10 Mar 2021 17:49:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	04 Sep 2020 17:47:39
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:26:54
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 17:47:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User entered empty.	System	10 Mar 2021 17:49:16
User entered 'l'	System	04 Sep 2020 17:47:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User entered empty.	System	10 Mar 2021 17:49:16
User entered '1'	System	04 Sep 2020 17:47:39



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:26
User entered empty.	System	10 Mar 2021 17:49:16
User entered '804 (804)'	System	04 Sep 2020 17:47:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
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)	11 Sep 2020 17:10:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 17:10:39
Data point term sent to Coder	System	11 Sep 2020 17:09:54
User entered 'Amoxicillin'	Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'Urinary Tract Infection'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered '1000'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'mg (mg)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'once daily (QD)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'Oral (ORAL)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered '08 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered '0'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:39:39
User entered 'No (N)' reason for change: New Information	(b) (4) Taylor Ladson (b) (4)	18 Sep 2020 16:39:39
User signature succeeded.	(b) (4) David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:13:53
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	18 Sep 2020 16:39:39
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 16:39:39
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	14 Sep 2020 04:49:45
	(b) (4)	
User entered empty.	Madhu Balachandran	11 Sep 2020 17:09:21
	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	14 Sep 2020 04:49:45
User entered 'No (N)'	(b) (4) Madhu Balachandran (b) (4)	11 Sep 2020 17:09:21



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
User entered 'I'	System	11 Sep 2020 17:09:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
User entered 'I'	System	11 Sep 2020 17:09:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:15
User entered '804 (804)'	System	11 Sep 2020 17:09:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
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)	28 Sep 2020 22:04:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:04:55
Data point term sent to Coder	System	28 Sep 2020 21:09:14
User entered 'Advil'	Hannah Yellin (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE, MYALGIA, ARTHRALGIA 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 or 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 FATIGUE, MYALGIA, ARTHRALGIA did not meet the AE reporting criteria.	(b) (4), (b) (6)	02 Nov 2020 08:47:28
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE, MYALGIA, ARTHRALGIA 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 or 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 FATIGUE, MYALGIA, ARTHRALGIA did not meet the AE reporting criteria.	Elissa Malkin (b) (4)	29 Oct 2020 20:35:23
' answered with 'solicited events: fatigue, myalgia, arthralgia do not meet AE reporting criteria' (Site from DM).	(b) (4)	

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE, MYALGIA, ARTHRALGIA 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 or 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 FATIGUE, MYALGIA, ARTHRALGIA did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) David Diemert (b) (4) (b) (4)	29 Oct 2020 09:47:13  29 Sep 2020 04:14:07
User entered 'Fatigue, chills, myalgia, arthralgia'	Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered '400'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'mg (mg)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:10:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'once daily (QD)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'Oral (ORAL)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered '17 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered '19 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:14:07
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	28 Sep 2020 21:09:12

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
User entered '1'	System	28 Sep 2020 21:09:12

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
User entered '1'	System	28 Sep 2020 21:09:12

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:40:08
User entered '804 (804)'	System	28 Sep 2020 21:09:12

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
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)	15 Dec 2020 17:29:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 17:29:54
Data point term sent to Coder	System	15 Dec 2020 17:29:22
User entered 'Amoxicillin'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Sinusitis'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '500'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:28:27



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '11 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:04:47
User entered 'No (N)' reason for change: New Information	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:04:47
User signature succeeded.	(b) (4) David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:09:56
Signature has been broken.	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:04:47
User entered '17 Dec 2020' reason for change: New Information	(b) (4) Taylor Ladson (b) (4)	15 Jan 2021 19:04:47
User signature succeeded.	(b) (4) David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 17:28:27

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
User entered '2'	System	15 Dec 2020 17:28:27

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
User entered 'I'	System	15 Dec 2020 17:28:27

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:36:46
User entered '804 (804)'	System	15 Dec 2020 17:28:27



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 16:06:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 16:06:55
Data point term sent to Coder	System	18 Dec 2020 16:05:44
User entered 'Influenza vaccine'	Erika Faust (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Flu prevention'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0.5'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'mL (mL)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'once (ONCE)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered '17 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User signature succeeded.	David Diemert (b) (4)	18 Dec 2020 16:13:48
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:04:49

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
User entered empty.	System	18 Dec 2020 16:04:49



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
User entered empty.	System	18 Dec 2020 16:04:49

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:04
User entered empty.	System	18 Dec 2020 16:04:49

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:57:02
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 Feb 2021 20:57:02
Data point term sent to Coder	System	25 Feb 2021 20:56:05
User entered 'Eliquis'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '5'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'twice daily (BID)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 20:55:22

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:55:22

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:57:01
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 Feb 2021 20:57:01
Data point term sent to Coder	System	25 Feb 2021 20:56:05
User entered 'aspirin'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '81'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:56:03

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Feb 2021 20:56:03

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 20:56:03

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:56:03

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:42:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:42:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Apr 2021 16:19:20
Data point term sent to Coder	System	05 Apr 2021 14:07:01
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:06:08
Coding entries removed.	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:06:08
Signature has been broken.	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:06:08
User entered 'AUGMENTIN (amoxicillin 500mg/clavulanic acid 125 mg)' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:06:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:39:20

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Augmentin'	Coder Import (b) (4) (b) (4) System Erika Faust (b) (4) (b) (4)	02 Mar 2021 09:39:20  25 Feb 2021 20:58:11 25 Feb 2021 20:57:11



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:10:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'community-acquired pneumonia'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:34:47
User signature succeeded.	David Diemert (b) (4)	05 Apr 2021 16:19:20
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Corrected.' (Site from DM).	David Diemert (b) (4)	05 Apr 2021 14:07:10
Signature has been broken.	David Diemert (b) (4)	05 Apr 2021 14:06:08
User entered '1' reason for change: New Information	David Diemert (b) (4)	05 Apr 2021 14:06:08
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:58:24
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
Signature has been broken.	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User entered '500' reason for change: New Information	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 22:12:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 22:12:47
DataPoint Un-verified.	David Diemert (b) (4)	17 Mar 2021 22:12:47
User entered 'Unknown' reason for change: Data Entry Error	David Diemert (b) (4)	17 Mar 2021 22:12:47
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:10:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 20:57:11
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	05 Apr 2021 16:19:20
Signature has been broken.	David Diemert (b) (4)	05 Apr 2021 14:06:08
User entered 'tablet (TABLET)' reason for change: Per Query Resolution	David Diemert (b) (4)	05 Apr 2021 14:06:08
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
Signature has been broken.	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User entered 'mg (mg)' reason for change: New Information	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 22:12:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 22:12:47
DataPoint Un-verified.	David Diemert (b) (4)	17 Mar 2021 22:12:47
User entered 'Other (OTHER)' reason for change: Per Query Resolution	David Diemert (b) (4)	17 Mar 2021 22:12:47
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 20:57:11
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
Signature has been broken.	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User entered empty; reason for change New Information	Erika Faust (b) (4)	19 Mar 2021 16:48:03
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Un-verified.	David Diemert (b) (4)	17 Mar 2021 22:12:47
User entered 'Unknown' reason for change: Per Query Resolution	David Diemert (b) (4)	17 Mar 2021 22:12:47
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'twice daily (BID)'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:57:11



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
DataPoint Un-verified.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
Signature has been broken.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
User entered 'No (N)' reason for change: New Information	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
DataPoint Un-verified.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
Signature has been broken.	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
User entered '28 Feb 2021' reason for change: New Information	(b) (4) Erika Faust (b) (4)	19 Mar 2021 16:48:03
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 20:57:11

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered '2'	System	25 Feb 2021 20:57:11



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered 'I'	System	25 Feb 2021 20:57:11

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered '804 (804)'	System	25 Feb 2021 20:57:11

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:39:09
Data point term sent to Coder	System	25 Feb 2021 20:58:10
User entered 'Furosemide'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '40'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:57:50

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Feb 2021 20:57:50

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 20:57:50

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:57:50

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 21:15:02
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 Feb 2021 21:15:02
Data point term sent to Coder	System	25 Feb 2021 20:59:11
User entered 'atorvastatin'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 10:51:29
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Please see MH#11. ' (Site from DM).	David Diemert (b) (4) (b) (4)	15 Mar 2021 17:14:11
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:35:30
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'hyperlipidemia'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '40'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'other (OTHER)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'QHS'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:58:31

**US3542029**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:58:31

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:58:31

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:58:31

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 21:01:00
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 Feb 2021 21:01:00
Data point term sent to Coder	System	25 Feb 2021 21:00:12
User entered 'Metoprolol'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '50'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '20 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 20:59:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Feb 2021 20:59:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 20:59:21

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:59:21



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA, PRODUCT: SODIUM ZIRCONIUM CYCLOSILICATE, PRODUCTSYNONYM: LOKELMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:02:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:02:07
Data point term sent to Coder	System	25 Feb 2021 21:01:12
User entered 'lokelma'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'hyperkalemia'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '5'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 08:37:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	16 Mar 2021 20:04:08
DataPoint Un-verified.	David Diemert (b) (4)	15 Mar 2021 17:29:55
User entered 'g (g)' reason for change: Per Query Resolution	David Diemert (b) (4)	15 Mar 2021 17:29:55
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:35:53
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'twice daily (BID)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:00:28



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:00:28

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User entered '2'	System	25 Feb 2021 21:00:28



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User entered 'I'	System	25 Feb 2021 21:00:28

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:29
User entered '804 (804)'	System	25 Feb 2021 21:00:28

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:08:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:08:11
Data point term sent to Coder	System	25 Feb 2021 21:02:13
User entered 'calcium gluconate'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'hyperkalemia'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'l'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'g (g)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:01:15



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Intravenous (INTRAVENOUS)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '20 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:01:15



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:01:15

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User entered 'I'	System	25 Feb 2021 21:01:15

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User entered 'I'	System	25 Feb 2021 21:01:15

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:20
User entered '804 (804)'	System	25 Feb 2021 21:01:15

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: PROPAFENONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 21:04:01
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 Feb 2021 21:04:01
Data point term sent to Coder	System	25 Feb 2021 21:03:14
User entered 'propafenone'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '150'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'other (OTHER)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Every 8 hours'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Feb 2021 21:02:41

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:02:41

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:02:41

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:02:41

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:50:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:50:57
Data point term sent to Coder	System	25 Feb 2021 21:04:16
User entered 'Ceftriaxone'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:10:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'community-acquired pneumonia'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'l'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'g (g)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Intravenous (INTRAVENOUS)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:03:40



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '21 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:03:40

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User entered 'I'	System	25 Feb 2021 21:03:40

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User entered 'I'	System	25 Feb 2021 21:03:40

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:59
User entered '804 (804)'	System	25 Feb 2021 21:03:40



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:26:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:26:58
Data point term sent to Coder	System	25 Feb 2021 21:05:17
User entered 'azithromycin'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'community-acquired pneumonia'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '500'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once (ONCE)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:04:26



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:04:26

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User entered empty.	System	25 Feb 2021 21:04:26



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User entered empty.	System	25 Feb 2021 21:04:26

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:56
User entered empty.	System	25 Feb 2021 21:04:26

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:06:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:06:02
Data point term sent to Coder	System	25 Feb 2021 21:05:21
User entered 'Toradol'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'abdominal pain'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '30'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:05:06



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once (ONCE)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Intravenous (INTRAVENOUS)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '18 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:05:06



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User entered empty.	System	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User entered empty.	System	25 Feb 2021 21:05:06

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:51
User entered empty.	System	25 Feb 2021 21:05:06

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:42:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:42:00
Data point term sent to Coder	System	25 Feb 2021 21:07:26
User entered 'azithromycin'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'community-acquired pneumonia'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '250'	Erika Faust (b) (4)	25 Feb 2021 21:07:02



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '20 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:07:02



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User entered 'I'	System	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User entered 'I'	System	25 Feb 2021 21:07:02

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:43
User entered '804 (804)'	System	25 Feb 2021 21:07:02

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Feb 2021 07:40:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Feb 2021 07:40:08
Data point term sent to Coder	System	25 Feb 2021 21:08:28
User entered 'Furosemide (lasix)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'atrial fibrillation'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:10:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '40'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Intravenous (INTRAVENOUS)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:07:39



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '20 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:07:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User entered 'I'	System	25 Feb 2021 21:07:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User entered 'I'	System	25 Feb 2021 21:07:39

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:46
User entered '804 (804)'	System	25 Feb 2021 21:07:39



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:10:01
Data point term sent to Coder	System	25 Feb 2021 21:09:28
User entered 'Heparin'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Yes (Y)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Deep Vein Thrombosis Prophylaxis'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '5000'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Other (OTHER)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Units'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'other (OTHER)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'every 8 hours'	Erika Faust (b) (4)	25 Feb 2021 21:08:56



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:08:56

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User entered empty.	System	25 Feb 2021 21:08:56



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User entered empty.	System	25 Feb 2021 21:08:56

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:21
User entered empty.	System	25 Feb 2021 21:08:56

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:11:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:11:01
Data point term sent to Coder	System	25 Feb 2021 21:10:30
User entered 'hydrochlorothiazide'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'hypertension'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '25'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:09:42



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'once daily (QD)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '20 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '22 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:09:42



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered 'I'	System	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered '1'	System	25 Feb 2021 21:09:42

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered '804 (804)'	System	25 Feb 2021 21:09:42

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:12:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:12:00
Data point term sent to Coder	System	25 Feb 2021 21:11:31
User entered 'Acetaminophen'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Abdominal pain'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '650'	Erika Faust (b) (4)	25 Feb 2021 21:10:32



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'other (OTHER)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Every 4 hours as needed'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:10:32



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '21 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User entered empty.	System	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User entered empty.	System	25 Feb 2021 21:10:32

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:37
User entered empty.	System	25 Feb 2021 21:10:32

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:05:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:05:37
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
Data point term sent to Coder	System	25 Feb 2021 21:11:33
User entered 'oxycodone'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'abdominal pain'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '5'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'mg (mg)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'other (OTHER)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'every 4 hours as needed'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'Oral (ORAL)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered empty.	Erika Faust (b) (4)	25 Feb 2021 21:11:08



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '19 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '0'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered '21 Feb 2021'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User signature succeeded.	David Diemert (b) (4)	18 Mar 2021 01:40:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:01
User entered 'No (N)'	Erika Faust (b) (4)	25 Feb 2021 21:11:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User entered empty.	System	25 Feb 2021 21:11:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User entered empty.	System	25 Feb 2021 21:11:08

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:29
User entered empty.	System	25 Feb 2021 21:11:08



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Mar 2021 16:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 16:47:51
Data point term sent to Coder	System	19 Mar 2021 16:46:22
User entered 'Xanax'	Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'PTSD'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'UNK'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Other (OTHER)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'UNKNOWN'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'as needed (PRN)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01



US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'UN UNK 2015'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:10:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Mar 2021 18:06:30
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 16:46:01



US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 16:46:01

US3542029

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 08:10:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 16:46:01

US3542029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:10:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:51:10
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:29:51
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4)	03 Feb 2021 18:36:42
	(b) (4)	

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'USA-US084-2021-MRNA-1273-P301000006'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'David'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Diemert'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '2300 Eye Street NW'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Washington'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '20037'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered 'US'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 15:31:09
User entered '2'	System	12 Mar 2021 15:51:50
User entered '1'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'USA-US084-2021-MRNA-1273-P301000006'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'David'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Diemert'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '2300 Eye Street NW'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Washington'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '20037'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered 'US'	System	25 Feb 2021 22:24:38



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 15:31:09
User entered '2'	System	12 Mar 2021 15:51:50
User entered '1'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:10:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered '25/Feb/2021 17:24'	System	25 Feb 2021 22:24:38

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:10:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered 'l'	(b) (4), (b) (6)	25 Feb 2021 22:24:38

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'USA-US084-2021-MRNA-1273-P301000006'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'David'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Diemert'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '2300 Eye Street NW'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Washington'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '20037'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered 'US'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 15:31:09
User entered '2'	System	12 Mar 2021 15:51:50
User entered '1'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:10:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:41
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:37
User entered '12/Mar/2021 07:51'	(b) (4) System	12 Mar 2021 15:51:50

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:10:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:38:37
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 15:51:50

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'USA-US084-2021-MRNA-1273-P301000006'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Yes (Y)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'No (N)'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'David'	System	25 Feb 2021 22:24:16

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:10:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Diemert'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '2300 Eye Street NW'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered 'Washington'	System	25 Feb 2021 22:24:16



**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:24:32
User entered '20037'	System	25 Feb 2021 22:24:16

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:30:57
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:27:01
User entered 'US'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:10:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 15:31:09
User entered '2'	System	12 Mar 2021 15:51:50
User entered '1'	System	25 Feb 2021 22:24:38

**US3542029**

**Folder: SAE USA-US084-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:10:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:41
User signature succeeded.	David Diemert (b) (4)	22 Mar 2021 19:21:54
User entered '22/Mar/2021 15:31'	(b) (4) System	22 Mar 2021 15:31:09

US3542029

Folder: SAE USA-US084-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:10:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:55:41
User signature succeeded.	David Diemert (b) (4)	22 Mar 2021 19:21:54
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 15:31:09