

US3242081 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:12:51

All time stamps listed in this document are displayed in GMT

US3242081

Form: Participant Creation

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

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Participant ID

US3242081

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

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US3242081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3242081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 08 Feb 2021 20:30:14

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 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) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Did the participant meet all eligibility criteria?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

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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) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

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

US3242081

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	NEUROPATHY, BILATERAL FEET
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3242081

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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 (5)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	ARRHYTHMIA
Start date (dd MMM yyyy)	10 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	10 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	SHOULDER PAIN, RIGHT
Start date (dd MMM yyyy)	13 MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	CORONARY ARTERY BYPASS GRAPT
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	PACEMAKER PLACEMENT
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	DEFIBRILLATOR PLACEMENT
Start date (dd MMM yyyy)	10 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	10 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Condition	CARDIAC ARREST
Start date (dd MMM yyyy)	18 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	18 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 14:14
Height (xxx.x)	73 in
Weight (xxx.x)	167 lb
BMI (xxx.x)	22.07906 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) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

### Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

Specify

ATTORNEY WITH IN OFFICE  
APPTS

### 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) 08 Feb 2021 20:30:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

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

Visit date (dd MMM yyyy)	13 AUG 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 186106

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) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Height	ND - Not Done
Weight	ND - Not Done

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

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)	13 AUG 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:01
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

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)	13 AUG 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:45
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3242081

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

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.*

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 16:12 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 16:12

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

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

Collection date (dd MMM yyyy)	13 AUG 2020
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Collection time (00:00-23:59)	15:47 (24 HR)
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Collection date and time (derived)	13 AUG 2020 15:47
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:45	13 AUG 2020 15:45
Nasopharyngeal Swab 2	No		



US3242081

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 17:00

PC Open Date & Time

13 AUG 2020 16:32

PC Close Date & Time

13 AUG 2020 19:02

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**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 94.9 °F

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

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

PC Time Stamp	13 AUG 2020 22:58
PC Open Date & Time	13 AUG 2020 19:57
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

14 AUG 2020 20:56

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

16 AUG 2020 00:42

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**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

97.0 °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

17 AUG 2020 21:47

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

18 AUG 2020 22:42

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.0 °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 01:28

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 17:01

PC Open Date & Time

13 AUG 2020 16:32

PC Close Date & Time

13 AUG 2020 19:02

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 23:00

PC Open Date & Time

13 AUG 2020 19:57

PC Close Date & Time

14 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**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

14 AUG 2020 20:58

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**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

16 AUG 2020 00:44

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 19:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**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

17 AUG 2020 21:49

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**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

18 AUG 2020 22:43

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**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

20 AUG 2020 01:30

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**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 ☐

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 17:02
PC Open Date & Time	13 AUG 2020 16:32
PC Close Date & Time	13 AUG 2020 19:02

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**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 ☐

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 23:01
PC Open Date & Time	13 AUG 2020 19:57
PC Close Date & Time	14 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**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 ☒

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 00:45
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 ☒

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:08
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**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 2339

EAB) (1725)

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:50
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:44
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**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

63 of 2339

EAB) (1725)



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 01:32
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3242081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

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

Visit date (dd MMM yyyy)	11 SEP 2020
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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	VISIT2
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US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:23
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	17:14 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:14
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

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.*

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:44

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

US3242081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 11 SEP 2020

Collection time (00:00-23:59) 16:19 (24 HR)

Collection date and time (derived) 11 SEP 2020 16:19

US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	11 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

US3242081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:28

PC Open Date & Time

11 SEP 2020 17:04

PC Close Date & Time

11 SEP 2020 19:34



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**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 98.1 °F

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

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

PC Time Stamp	11 SEP 2020 22:17
PC Open Date & Time	11 SEP 2020 20:29
PC Close Date & Time	12 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 01:27

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 02:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 01:34

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:07

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 01:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**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

11 SEP 2020 17:29

PC Open Date & Time

11 SEP 2020 17:04

PC Close Date & Time

11 SEP 2020 19:34



US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 22:19

PC Open Date & Time

11 SEP 2020 20:29

PC Close Date & Time

12 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**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

13 SEP 2020 01:29

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**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

14 SEP 2020 02:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**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

15 SEP 2020 01:34

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 22:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 23:08

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**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

18 SEP 2020 01:22

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**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 ☐



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:30
PC Open Date & Time	11 SEP 2020 17:04
PC Close Date & Time	11 SEP 2020 19:34

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**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 ☐

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:21
PC Open Date & Time	11 SEP 2020 20:29
PC Close Date & Time	12 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**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)

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 01:30
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 02:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**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 ☒



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 01:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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)

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:04
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 ☒

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 23:09
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 01:23
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3242081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3242081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:47 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:47
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

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.*



US3242081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 13 OCT 2020

Collection time (00:00-23:59) 15:33 (24 HR)

Collection date and time (derived) 13 OCT 2020 15:33

US3242081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:34:49

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 15:00:31

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

21 OCT 2020 15:15:13

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 18:00:04

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 08:38:04

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 17:15:35
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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 <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	23 NOV 2020 19:13:31
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59



US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 NOV 2020 18:55:34
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 21:08:26

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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	12 DEC 2020 00:02:38
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

19 DEC 2020 00:03:06

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

26 DEC 2020 00:02:54

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:03:48

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

09 JAN 2021 01:59:59

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

18 JAN 2021 10:36:35

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59



US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 02:46:32

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

30 JAN 2021 10:17:40

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 01:45:02

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:27:51

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 00:50:44
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 00:36:21
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

08 MAR 2021 19:57:30

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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

13 MAR 2021 00:04:08

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59



US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 01:47:19

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 MAR 2021 08:40:15
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	03 APR 2021 12:35:24
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 APR 2021 14:12:15
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:03:34

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 02:17:56

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

<b>TIMEPOINT</b>	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 16:42:52
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAY 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2021 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 FEB 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 MAR 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 APR 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAY 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**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 ☐

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

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

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[Patient Cloud Open Date & Time](#)

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15 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 OCT 2022 23:59

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US3242081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:12:51

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		08 MAR 2021 19:56:43



US3242081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:14

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3242081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 00:26:29

Generated On: 09 Jun 2021 16:12:51

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

Visit date (dd MMM yyyy)	09 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
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US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:41:56

Generated On: 09 Jun 2021 16:12:51

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) \_\_\_\_\_

US3242081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 00:26:29

Generated On: 09 Jun 2021 16:12:51

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.*

US3242081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 00:26:29

Generated On: 09 Jun 2021 16:12:51

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

Collection date (dd MMM yyyy)	09 MAR 2021
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Collection time (00:00-23:59)	15:00 (24 HR)
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Collection date and time (derived)	09 MAR 2021 15:00
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US3242081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 00:26:29

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 13:01:38

Generated On: 09 Jun 2021 16:12:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3242081

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 13:01:38

Generated On: 09 Jun 2021 16:12:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3242081**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

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*



**US3242081**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242081

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:51

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"/>

**US3242081**

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

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

**Generated On: 09 Jun 2021 16:12:51**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3242081

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 06 JAN 2021

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

Folder OID UNBLND\_DECIDE

US3242081

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 15:58:08

Generated On: 09 Jun 2021 16:12:51

Date of updated informed consent (dd MMM yyyy) 06 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) 06 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 \_\_\_\_\_

US3242081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 06 JAN 2021

Collection time (00:00-23:59) 15:38 (24 HR)

Collection date and time (derived) 06 JAN 2021 15:38

US3242081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	15:35
Collection Date and Time (derived)	06 JAN 2021 15:35

US3242081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Feb 2021 20:30:13

Generated On: 09 Jun 2021 16:12:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.



US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

AEID

Adverse event

INSECT BITES TO LEFT LEG

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)

05 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)

18 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

328 of 2339

EAB) (1725)

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

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)	_____

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

AEID	USA-US067-2021-MRNA-1273-P30 1000012
Adverse event	SEVERE SEPSIS
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)	01 APR 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)	03 APR 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 APR 2021
Hospital Discharge Date (dd MMM yyyy)	03 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

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	

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

---

SUBJECT DEVELOPED  
ENTERITIS REQUIRING  
HOSPITALIZATION. HAS  
RESOLVED AND SUBJECT HAS  
BEEN DISCHARGED. MED  
RECORDS REQUESTED.  
RECORDS RECEIVED, UPDATED  
SAE AND AE AND CONMEDS,  
RECORDS SHOWS NEGATIVE  
COVID TEST.

---

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

---

US3242081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

AEID	
Adverse event	ENTERITIS
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)	01 APR 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)	03 APR 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	

US3242081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

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)	_____

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

AEID

Adverse event

HYPONATREMIA

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)

01 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 APR 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 (4)

Data signed: (b) (4) 20 Apr 2021 21:17:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Feb 2021 20:30:13

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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) 20 Apr 2021 21:17:44

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Name of Medication ATENOLOL

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 (1)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 1994
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 (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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	2000
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 (3)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐  
No ☒

Indication INSECT BITES TO LEFT LEG

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 (3)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 21:17:44

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Name of Medication LYRICA

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY, BILATERAL FEET

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 21:17:44

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
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 (5)

Data signed: (b) (4) 20 Apr 2021 21:17:44

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Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 21:17:44

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Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication CAD

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 1994	
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 (8)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication VITAMIN B-12

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 (10)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN SUPPLEMENT

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) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 (11)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication NACL

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS

Dose per administration 0.9

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

If dose unit is Other, specify PERCENT

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 APR 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 (13)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication IOPAMIDOL

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS(PREVENT)

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 APR 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 (15)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication ONDANSETRON

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS PREVENTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 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 (16)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS PREVENTION

Dose per administration 3.375

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) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 APR 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 (17)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS PREVENTION

Dose per administration 4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 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 (18)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication PREGABALIN

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS PREVENTION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 APR 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 (19)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒  
No ☐

Indication SEVERE SEPSIS PREVENTION

Dose per administration 0.9

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

If dose unit is Other, specify PERCENT

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 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 (20)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication ENTERITIS

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 (20)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		03 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 APR 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"/>

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication CYANOCOBALAMIN

Prophylaxis Yes ☐  
No ☒

Indication SEVERE SEPSIS

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 ☐

PRODUCTION RELEASE (v12.003

378 of 2339

EAB) (1725)

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		03 APR 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"/>

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ENTERITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

380 of 2339

EAB) (1725)

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

	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)		03 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 20 Apr 2021 21:17:44

Generated On: 09 Jun 2021 16:12:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 APR 2021	CHEST PA, AP FLAT, AND UPRIGHT ABDOMINAL	Adverse Event	
01 APR 2021	CT ABDOMEN PELVIS WITH IV CONTRAST ONLY	Adverse Event	
01 APR 2021	CT CHEST PULMONARY EMBOLISM WITH CONTRAST	Adverse Event	
01 APR 2021	XRAY, ACUTE ABDOMINAL SERIES WITH CHEST	Adverse Event	



US3242081

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:12:51

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

US3242081

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:12:51

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 ☐

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:11:32

Generated On: 09 Jun 2021 16:12:51

SAEID	USA-US067-2021-MRNA-1273-P301000012
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:11:32

Generated On: 09 Jun 2021 16:12:51

SAEID	USA-US067-2021-MRNA-1273-P301000012
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 11:38
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

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 14:11:32

Generated On: 09 Jun 2021 16:12:51

SAEID	USA-US067-2021-MRNA-1273-P301000012
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/APR/2021 12:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 14:11:32

Generated On: 09 Jun 2021 16:12:51

SAEID	USA-US067-2021-MRNA-1273-P301000012
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/APR/2021 06:09
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

US3242081 (Prod: Clinical Research Atlanta - ERN-PPDS)

**US3242081**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:12:51**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'US3242081'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:49:50



US3242081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:23

US3242081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:49:51

US3242081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:23

**US3242081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'SCRN'	(b) (4), (b) (6) System	13 Aug 2020 19:39:23

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:49:52

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '76'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

**US3242081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:51**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'YEARS'	(b) (4), (b) (6) System	13 Aug 2020 19:39:46

**US3242081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:51**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '76'	(b) (4), (b) (6) System	13 Aug 2020 19:39:58



US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Male (M)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

**US3242081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:51**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'I'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46



US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:51

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:46

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58

**US3242081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:51**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Aug 2020'	(b) (4), (b) (6) System	13 Aug 2020 19:39:58

**US3242081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:51**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2020'	(b) (4), (b) (6) System	13 Aug 2020 19:39:58

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Amendment 2 (2)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58



**US3242081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:51**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 19:39:58

US3242081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:49:51

**US3242081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:51**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'I'	(b) (4), (b) (6) System	13 Aug 2020 19:40:02

US3242081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:12:51

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 19:40:02

US3242081

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:12:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:29

US3242081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:13
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:14:49
User entered 'Hypertension'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49



US3242081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49

US3242081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49

US3242081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49

**US3242081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49

US3242081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:49

**US3242081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6) System	13 Aug 2020 20:14:49

**US3242081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6) System	13 Aug 2020 20:14:49

**US3242081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:14:49



**US3242081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:14:49

US3242081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:14
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:15:50
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

US3242081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 2000'	(b) (4), (b) (6) System	13 Aug 2020 20:15:03



**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2000'	(b) (4), (b) (6) System	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:03

**US3242081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:03

US3242081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY(i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:59:50
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
Query 'Per DM CLR: Please verify the type of the NEUROPATHY(i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'unknown' (Site from DM).	Donna Toepfer (b) (4)	17 Sep 2020 16:42:33
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY(i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 04:03:17
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:35:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:35:16
Data point term sent to Coder	System	13 Aug 2020 20:15:51
User entered 'Neuropathy, bilateral feet'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25

**US3242081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1995'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25

US3242081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25

US3242081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25

US3242081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25



US3242081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:25

**US3242081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1995'	(b) (4), (b) (6) System	13 Aug 2020 20:15:25

**US3242081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1995'	(b) (4), (b) (6) System	13 Aug 2020 20:15:25

**US3242081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:25

**US3242081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:25

US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:16:14
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:15:51
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48

US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 2015'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48

US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48



US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48

US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48

US3242081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:15:48

**US3242081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 2015'	(b) (4), (b) (6) System	13 Aug 2020 20:15:48

**US3242081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2015'	(b) (4), (b) (6) System	13 Aug 2020 20:15:48

**US3242081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:48

**US3242081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:15:48

US3242081

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:18:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:18:16
Data point term sent to Coder	System	13 Aug 2020 20:16:53
User entered 'Coronary Artery Disease'	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01



US3242081

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User closed query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #8 CORONARY ARTERY BYPASS GRAFT done last UN UNK 1994 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:59:13
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
Query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #8 CORONARY ARTERY BYPASS GRAFT done last UN UNK 1994 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	17 Sep 2020 16:47:01
User entered 'UN UNK 1994' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Sep 2020 16:46:52
User opened query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #8 CORONARY ARTERY BYPASS GRAFT done last UN UNK 1994 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 04:14:50
User entered 'UN UNK 2012'	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01

US3242081

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:46:52
User entered 'Jan 2012'	System	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:46:52
User entered '2012'	System	13 Aug 2020 20:16:01

**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:16:01



**US3242081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:16:01

US3242081

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User closed query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:57:41
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
Query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Update accordingly. ' answered with 'unknown' (Site from DM).	Donna Toepfer (b) (4)	17 Sep 2020 16:47:24
User opened query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 04:16:08
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:19:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:19:19
Data point term sent to Coder	System	13 Aug 2020 20:17:57
User entered 'Arrhythmia'	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

US3242081

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '10 May 2018'	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Aug 2020 21:29:46
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Aug 2020 21:29:46
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 20:17:50
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Aug 2020 20:17:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Aug 2020 20:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:17:42
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '10 May 2018'	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

**US3242081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:17:42

**US3242081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	13 Aug 2020 20:17:42



**US3242081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	13 Aug 2020 20:17:42

**US3242081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	13 Aug 2020 20:17:42

**US3242081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	13 Aug 2020 20:17:42

US3242081

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:37:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 06:37:22
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:18:59
User entered 'Shoulder pain, right'	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 May 2020'	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19

US3242081

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19

US3242081

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:12:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19



**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2020'	(b) (4), (b) (6) System	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2020'	(b) (4), (b) (6) System	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:18:19

**US3242081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 20:18:19

US3242081

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:00:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:00:12
Data point term sent to Coder	System	13 Aug 2020 20:22:07
User entered 'CORONARY ARTERY BYPASS GRAPt' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Aug 2020 20:21:13
Data point term sent to Coder	System	13 Aug 2020 20:20:02
User entered 'Coronary Artery Bypass Graph'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22



US3242081

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22

US3242081

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:22

**US3242081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:22

US3242081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Surgical and medical procedures, HLG: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:21:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:21:08
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:20:02
User entered 'Pacemaker Placement'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45



US3242081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45

US3242081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45

US3242081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45

**US3242081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45

US3242081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:19:45

**US3242081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:45

**US3242081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:45

**US3242081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:45



**US3242081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '1994'	(b) (4), (b) (6) System	13 Aug 2020 20:19:45

US3242081

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:22:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:22:10
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 20:21:03
User entered 'Coronary Artery Bypass Graft'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

US3242081

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Un UNK 2010'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

US3242081

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'UN UNK 2010'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 2010'	(b) (4), (b) (6) System	13 Aug 2020 20:20:07



**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2010'	(b) (4), (b) (6) System	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'Jan 2010'	(b) (4), (b) (6) System	13 Aug 2020 20:20:07

**US3242081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2010'	(b) (4), (b) (6) System	13 Aug 2020 20:20:07

US3242081

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:12:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User coded data point as SOC: Surgical and medical procedures, HLG: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 05:39:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 05:39:14
Data point term sent to Coder	System	13 Aug 2020 20:21:03
User entered 'Defibrillator Placement'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '10 May 2018'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43

US3242081

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43

US3242081

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:12:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '10 May 2018'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43



**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	13 Aug 2020 20:20:43

**US3242081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	13 Aug 2020 20:20:43

US3242081

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:12:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardiac arrest, LLT: Cardiac arrest - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 18:06:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 18:06:47
	(b) (4)	
Data point term sent to Coder System	System	20 Apr 2021 18:05:39
User entered 'Cardiac Arrest'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '18 May 2018'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45



**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '18 May 2018'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'May 2018'	(b) (4), (b) (6) System	20 Apr 2021 18:04:45

**US3242081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '2018'	(b) (4), (b) (6) System	20 Apr 2021 18:04:45

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04



US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '14:14'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '13 Aug 2020 14:14'	(b) (4), (b) (6) System	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '73' in	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04
DataPoint set to visible.	System	13 Aug 2020 19:40:02

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '167' lb	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04
DataPoint set to visible.	System	13 Aug 2020 19:40:02

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '22.07906'	(b) (4), (b) (6)	01 Oct 2020 14:13:04
DataPoint set to visible.	System	13 Aug 2020 19:40:02

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'kg/m2'	(b) (4), (b) (6)	01 Oct 2020 14:13:04
DataPoint set to visible.	System	13 Aug 2020 19:40:02

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04



US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'bpm'	(b) (4), (b) (6) System	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 14:13:04



US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:04

**US3242081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 14:13:04

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:38:58

US3242081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:38:58

US3242081

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:17

US3242081

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:17

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55



US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'attorney with in office appts'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55



US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'I'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '0'	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

US3242081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	01 Oct 2020 14:13:55

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 19:40:12

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 19:40:12

US3242081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	13 Aug 2020 19:40:12

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'VISIT1'	System	13 Aug 2020 19:40:12

US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:49:38



US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:17:53
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:17:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 19:49:38
User entered '186106' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:49:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:49:38

US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:19

US3242081

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:19

US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:19

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:12:51**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:19

US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:19

US3242081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:51

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	01 Oct 2020 14:14:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:07:08



US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query '	(b) (4), (b) (6)	02 Sep 2020 13:52:47
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 17:38:51
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:10:15
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '73' in	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:52:51
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:10:19
User entered '167' lb	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query '	(b) (4), (b) (6)	02 Sep 2020 13:52:47
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 17:38:51
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:10:15
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '73' in	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:52:51
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:10:19
User entered '167' lb	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '15:01'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Aug 2020 15:01'	(b) (4), (b) (6)	13 Aug 2020 21:23:36
	System	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '97.5' F	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '70'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'bpm'	System	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '14'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '120'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '70'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query '	(b) (4), (b) (6)	02 Sep 2020 13:52:47
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 17:38:51
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:10:15
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '73' in	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:52:51
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:38:46
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:10:19
User entered '167' lb	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
	(b) (4), (b) (6)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 11:58:24
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	13 Aug 2020 21:23:43
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 21:23:36
User entered '16:45'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Aug 2020 16:45'	(b) (4), (b) (6)	
	System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '97.5' F	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '60'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'bpm'	System	13 Aug 2020 21:23:36



US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '16'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '130'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '78'	Donna Toepfer (b) (4)	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 21:23:36

US3242081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:01:28

US3242081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:01:28



US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	13 Aug 2020 20:21:57
	System	

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '16:12'	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Aug 2020 16:12'	(b) (4), (b) (6)	13 Aug 2020 20:21:57
	System	

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	13 Aug 2020 20:21:57



US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'ONCE'	System	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:01

US3242081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:01

US3242081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:52
User entered '15:47'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:01

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Aug 2020 15:47'	(b) (4), (b) (6)	13 Aug 2020 20:02:01
	System	

US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '13 Aug 2020'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18



US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered '15:45'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Aug 2020 15:45'	(b) (4), (b) (6)	
	System	13 Aug 2020 20:02:18

US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

US3242081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:02:18

**US3242081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:02:18
	System	

US3242081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:02:21



US3242081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	System	13 Aug 2020 20:02:21

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:00:08', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'd165ea46-131e-4407-8f3b-038a0c1ba523'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Aug 2020 21:00:19

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T16:59:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'd165ea46-131e-4407-8f3b-038a0c1ba523' User entered '97.5'	(b) (4), (b) (6) System	13 Aug 2020 21:00:19
	System	13 Aug 2020 21:00:19

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T16:59:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'd165ea46-131e-4407-8f3b-038a0c1ba523'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Aug 2020 21:00:19

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:00:16', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'd165ea46-131e-4407-8f3b-038a0c1ba523'	(b) (4), (b) (6)	
	System	13 Aug 2020 21:00:19
User entered '13 Aug 2020 17:00'	System	13 Aug 2020 21:00:19

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 16:32'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:02'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:57:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb43f3c1-6843-40b5-b6d8-d6d4e1935949' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Aug 2020 02:59:12
	System	14 Aug 2020 02:59:12

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:57:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb43f3c1-6843-40b5-b6d8-d6d4e1935949' User entered '94.9'	(b) (4), (b) (6) System	14 Aug 2020 02:59:12
	System	14 Aug 2020 02:59:12

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:58:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb43f3c1-6843-40b5-b6d8-d6d4e1935949'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 02:59:12

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:58:59', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb43f3c1-6843-40b5-b6d8-d6d4e1935949' User entered '13 Aug 2020 22:58'	(b) (4), (b) (6) System	14 Aug 2020 02:59:12
	System	14 Aug 2020 02:59:12

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:57'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 2'	System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:56:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'de3c9e82-f8c4-4d5f-89b7-81dbe03e59b9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 00:56:51
	System	15 Aug 2020 00:56:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:56:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'de3c9e82-f8c4-4d5f-89b7-81dbe03e59b9' User entered '96.0'	(b) (4), (b) (6) System	15 Aug 2020 00:56:51
	System	15 Aug 2020 00:56:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:56:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'de3c9e82-f8c4-4d5f-89b7-81dbe03e59b9'	(b) (4), (b) (6)	
	System	15 Aug 2020 00:56:51
User entered 'No (N)'	System	15 Aug 2020 00:56:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:56:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'de3c9e82-f8c4-4d5f-89b7-81dbe03e59b9'	(b) (4), (b) (6)	
	System	15 Aug 2020 00:56:51
User entered '14 Aug 2020 20:56'	System	15 Aug 2020 00:56:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 3'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:42:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c41e591a-da0d-4be6-b14b-4e9729d56b5f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 04:42:44
	System	16 Aug 2020 04:42:44



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:42:28', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c41e591a-da0d-4be6-b14b-4e9729d56b5f' User entered '96.0'	(b) (4), (b) (6) System	16 Aug 2020 04:42:44
	System	16 Aug 2020 04:42:44

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:42:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c41e591a-da0d-4be6-b14b-4e9729d56b5f' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 04:42:44
	System	16 Aug 2020 04:42:44

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:42:47', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c41e591a-da0d-4be6-b14b-4e9729d56b5f' User entered '16 Aug 2020 00:42'	(b) (4), (b) (6) System	16 Aug 2020 04:42:44
	System	16 Aug 2020 04:42:44

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 4'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:05:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'a251f2c2-e165-4661-b29c-4d3b22c8014a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 23:05:51
	System	16 Aug 2020 23:05:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:05:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'a251f2c2-e165-4661-b29c-4d3b22c8014a' User entered '97.2'	(b) (4), (b) (6) System	16 Aug 2020 23:05:51
	System	16 Aug 2020 23:05:51



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:05:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'a251f2c2-e165-4661-b29c-4d3b22c8014a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 23:05:51
	System	16 Aug 2020 23:05:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:05:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'a251f2c2-e165-4661-b29c-4d3b22c8014a' User entered '16 Aug 2020 19:05'	(b) (4), (b) (6) System	16 Aug 2020 23:05:51
	System	16 Aug 2020 23:05:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 5'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:46:45', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '347bab11-e92e-4f11-a0b8-eb11a788b002' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 01:47:47
	System	18 Aug 2020 01:47:47

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:46:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '347bab11-e92e-4f11-a0b8-eb11a788b002' User entered '97.0'	(b) (4), (b) (6) System	18 Aug 2020 01:47:47
	System	18 Aug 2020 01:47:47

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:47:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '347bab11-e92e-4f11-a0b8-eb11a788b002'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Aug 2020 01:47:47



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:47:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '347bab11-e92e-4f11-a0b8-eb11a788b002'	(b) (4), (b) (6)	
User entered '17 Aug 2020 21:47'	System	18 Aug 2020 01:47:47

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 6'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:41:57', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6d68864c-7de5-4b91-b417-da61c35a3c8f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 02:34:51
	System	19 Aug 2020 02:34:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6d68864c-7de5-4b91-b417-da61c35a3c8f' User entered '96.2'	(b) (4), (b) (6) System	19 Aug 2020 02:34:51
	System	19 Aug 2020 02:34:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:20', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6d68864c-7de5-4b91-b417-da61c35a3c8f' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 02:34:51
	System	19 Aug 2020 02:34:51

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6d68864c-7de5-4b91-b417-da61c35a3c8f' User entered '18 Aug 2020 22:42'	(b) (4), (b) (6) System	19 Aug 2020 02:34:51
	System	19 Aug 2020 02:34:51



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 7'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:28:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '14eba3a0-96b9-47af-b3a1-6d0d2c02c95b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 05:28:50
	System	20 Aug 2020 05:28:50

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:28:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '14eba3a0-96b9-47af-b3a1-6d0d2c02c95b' User entered '95.0'	(b) (4), (b) (6) System	20 Aug 2020 05:28:50
	System	20 Aug 2020 05:28:50

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:28:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '14eba3a0-96b9-47af-b3a1-6d0d2c02c95b'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 05:28:50

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:28:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '14eba3a0-96b9-47af-b3a1-6d0d2c02c95b' User entered '20 Aug 2020 01:28'	(b) (4), (b) (6) System	20 Aug 2020 05:28:50
	System	20 Aug 2020 05:28:50

US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:00:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8a5385aa-32b6-4dd2-a89f-455787f5c711' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 21:01:09
	System	13 Aug 2020 21:01:09

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:00:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8a5385aa-32b6-4dd2-a89f-455787f5c711' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 21:01:09
	System	13 Aug 2020 21:01:09

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:00:58', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8a5385aa-32b6-4dd2-a89f-455787f5c711' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 21:01:09
	System	13 Aug 2020 21:01:09

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8a5385aa-32b6-4dd2-a89f-455787f5c711' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 21:01:09
	System	13 Aug 2020 21:01:09

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8a5385aa-32b6-4dd2-a89f-455787f5c711' User entered '13 Aug 2020 17:01'	(b) (4), (b) (6) System	13 Aug 2020 21:01:09
	System	13 Aug 2020 21:01:09

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 16:32'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:02'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:59:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb3904d3-2b39-4dc0-8a5d-4a472f939627'	(b) (4), (b) (6)	
User entered 'None (1)'	System	14 Aug 2020 03:00:16

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:59:21', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb3904d3-2b39-4dc0-8a5d-4a472f939627'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 03:00:16

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:59:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb3904d3-2b39-4dc0-8a5d-4a472f939627'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 03:00:16

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T22:59:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb3904d3-2b39-4dc0-8a5d-4a472f939627'	(b) (4), (b) (6)	
User entered 'None (1)'	System	14 Aug 2020 03:00:16

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:18', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cb3904d3-2b39-4dc0-8a5d-4a472f939627'	(b) (4), (b) (6)	
	System	14 Aug 2020 03:00:16
User entered '13 Aug 2020 23:00'	System	14 Aug 2020 03:00:16

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:57'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 2'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:57:16', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3dae916d-4397-4b05-be5f-7bc1c22b622'	(b) (4), (b) (6)	
	System	15 Aug 2020 00:58:20
User entered 'None (1)'	System	15 Aug 2020 00:58:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:57:21', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3dae916d-4397-4b05-be5f-7bcb1c22b622'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Aug 2020 00:58:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:57:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3dae916d-4397-4b05-be5f-7bcb1c22b622'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Aug 2020 00:58:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:58:05', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3dae916d-4397-4b05-be5f-7bcb1c22b622'	(b) (4), (b) (6)	
	System	15 Aug 2020 00:58:20
User entered 'None (1)'	System	15 Aug 2020 00:58:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:58:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3dae916d-4397-4b05-be5f-7bcb1c22b622'	(b) (4), (b) (6)	
	System	15 Aug 2020 00:58:20
User entered '14 Aug 2020 20:58'	System	15 Aug 2020 00:58:20

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 3'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:43:14', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'daaf6078-a4c6-4434-85ad-294cad6decf1'	(b) (4), (b) (6)	
	System	16 Aug 2020 04:44:08
User entered 'None (1)'	System	16 Aug 2020 04:44:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:43:47', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'daaf6078-a4c6-4434-85ad-294cad6decf1' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 04:44:08
	System	16 Aug 2020 04:44:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:43:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'daaf6078-a4c6-4434-85ad-294cad6decf1' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 04:44:08
	System	16 Aug 2020 04:44:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'daaf6078-a4c6-4434-85ad-294cad6decf1'	(b) (4), (b) (6)	
	System	16 Aug 2020 04:44:08
User entered 'None (1)'	System	16 Aug 2020 04:44:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'daaf6078-a4c6-4434-85ad-294cad6decf1' User entered '16 Aug 2020 00:44'	(b) (4), (b) (6) System	16 Aug 2020 04:44:08
	System	16 Aug 2020 04:44:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 4'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:06:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e5a12855-75b4-4e39-b73d-fe44d708627a' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 23:07:12
	System	16 Aug 2020 23:07:12

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:06:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e5a12855-75b4-4e39-b73d-fe44d708627a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 23:07:12
	System	16 Aug 2020 23:07:12

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:06:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e5a12855-75b4-4e39-b73d-fe44d708627a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 23:07:12
	System	16 Aug 2020 23:07:12

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e5a12855-75b4-4e39-b73d-fe44d708627a' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 23:07:12
	System	16 Aug 2020 23:07:12

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:14', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e5a12855-75b4-4e39-b73d-fe44d708627a' User entered '16 Aug 2020 19:07'	(b) (4), (b) (6) System	16 Aug 2020 23:07:12
	System	16 Aug 2020 23:07:12

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 5'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:48:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '9aa8c761-7891-4fc0-abea-5c8cc90af3c4'	(b) (4), (b) (6)	
User entered 'None (1)'	System	18 Aug 2020 01:49:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:48:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '9aa8c761-7891-4fc0-abea-5c8cc90af3c4' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:49:20
	System	18 Aug 2020 01:49:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:48:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '9aa8c761-7891-4fc0-abea-5c8cc90af3c4' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:49:20
	System	18 Aug 2020 01:49:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:08', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '9aa8c761-7891-4fc0-abea-5c8cc90af3c4'	(b) (4), (b) (6)	
	System	18 Aug 2020 01:49:20
User entered 'None (1)'	System	18 Aug 2020 01:49:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:24', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '9aa8c761-7891-4fc0-abea-5c8cc90af3c4' User entered '17 Aug 2020 21:49'	(b) (4), (b) (6) System	18 Aug 2020 01:49:20
	System	18 Aug 2020 01:49:20

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 6'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b4c7d0ad-e38b-415a-9676-12832b8e8249' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 02:35:38
	System	19 Aug 2020 02:35:38

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:45', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b4c7d0ad-e38b-415a-9676-12832b8e8249' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 02:35:38
	System	19 Aug 2020 02:35:38

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:49', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b4c7d0ad-e38b-415a-9676-12832b8e8249' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 02:35:38
	System	19 Aug 2020 02:35:38

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:42:55', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b4c7d0ad-e38b-415a-9676-12832b8e8249' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 02:35:38
	System	19 Aug 2020 02:35:38

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b4c7d0ad-e38b-415a-9676-12832b8e8249' User entered '18 Aug 2020 22:43'	(b) (4), (b) (6) System	19 Aug 2020 02:35:38
	System	19 Aug 2020 02:35:38

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 7'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:29:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5f2fe1dd-c712-4ee2-b7d2-b711dd155f72'	(b) (4), (b) (6)	
	System	20 Aug 2020 05:30:08
User entered 'None (1)'	System	20 Aug 2020 05:30:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:29:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5f2fe1dd-c712-4ee2-b7d2-b711dd155f72'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 05:30:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:29:41', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5f2fe1dd-c712-4ee2-b7d2-b711dd155f72'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 05:30:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:29:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5f2fe1dd-c712-4ee2-b7d2-b711dd155f72' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 05:30:08
	System	20 Aug 2020 05:30:08

US3242081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5f2fe1dd-c712-4ee2-b7d2-b711dd155f72'	(b) (4), (b) (6)	
	System	20 Aug 2020 05:30:08
User entered '20 Aug 2020 01:30'	System	20 Aug 2020 05:30:08

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:18', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:32', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:01:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T17:02:01', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1b89d78-5797-4903-b00a-aebca7c55569' User entered '13 Aug 2020 17:02'	(b) (4), (b) (6) System	13 Aug 2020 21:02:00
	System	13 Aug 2020 21:02:00

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 16:32'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:02'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:41', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:46', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:00:57', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:01:08', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-13T23:01:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '61cc5004-252c-40ec-94ba-00ea60e39873' User entered '13 Aug 2020 23:01'	(b) (4), (b) (6) System	14 Aug 2020 03:01:22
	System	14 Aug 2020 03:01:22

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Aug 2020 19:57'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 2'	System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:58:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:58:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:02', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-14T20:59:59', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0509f8d3-fc1e-4897-9d9c-ec094f2081f6' User entered '14 Aug 2020 20:59'	(b) (4), (b) (6) System	15 Aug 2020 00:59:57
	System	15 Aug 2020 00:59:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 3'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce'	(b) (4), (b) (6)	
	System	16 Aug 2020 04:45:32
User entered 'No interference with activity (1)'	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:45', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce'	(b) (4), (b) (6)	
User entered 'No interference with activity (1)'	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:44:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:45:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:45:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:45:13', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T00:45:36', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '63631713-cec4-4a28-b3d4-062d8456c3ce' User entered '16 Aug 2020 00:45'	(b) (4), (b) (6) System	16 Aug 2020 04:45:32
	System	16 Aug 2020 04:45:32

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 4'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:32', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:40', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:07:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-16T19:08:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7b01f998-12ff-48b6-8ac9-43b1760830af' User entered '16 Aug 2020 19:08'	(b) (4), (b) (6) System	16 Aug 2020 23:08:07
	System	16 Aug 2020 23:08:07

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 5'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:32', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:49:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-17T21:50:18', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '982e71c3-1ead-45ec-badb-b0713710d02a' User entered '17 Aug 2020 21:50'	(b) (4), (b) (6) System	18 Aug 2020 01:50:15
	System	18 Aug 2020 01:50:15

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 6'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:40', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:47', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:43:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:44:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-18T22:44:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '6aee0038-9404-461e-83ae-109beb92f44e' User entered '18 Aug 2020 22:44'	(b) (4), (b) (6) System	19 Aug 2020 02:36:52
	System	19 Aug 2020 02:36:52

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 7'	System	13 Aug 2020 20:21:57

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:18', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03



US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:30:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:31:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

US3242081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-08-20T01:32:02', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '517cf7e7-87ee-4cb5-9eed-e2e5e79c876a' User entered '20 Aug 2020 01:32'	(b) (4), (b) (6) System	20 Aug 2020 05:32:03
	System	20 Aug 2020 05:32:03

**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57



**US3242081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 20:21:57

**US3242081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Aug 2020 22:03:15
	(b) (4)	

US3242081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered '21 Aug 2020'	Grace Newville (b) (4)	21 Aug 2020 22:03:15
	(b) (4)	

US3242081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	21 Aug 2020 22:03:15
	(b) (4)	

US3242081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Grace Newville (b) (4)	21 Aug 2020 22:03:15
	(b) (4)	

US3242081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Aug 2020 22:03:08
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 22:03:08
	System	

**US3242081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	01 Sep 2020 14:15:49
	(b) (4)	



US3242081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
	(b) (4), (b) (6)	
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 09:58:08
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Subject did not return phone calls until 9/1, two days out of day 15 PC window' (Site from System).	Grace Newville (b) (4)	01 Sep 2020 14:16:26
	(b) (4)	
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Sep 2020 14:15:49
User entered '1 Sep 2020'	Grace Newville (b) (4)	01 Sep 2020 14:15:49
	(b) (4)	

US3242081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	01 Sep 2020 14:15:49
	(b) (4)	

US3242081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Grace Newville (b) (4)	01 Sep 2020 14:15:49
	(b) (4)	

US3242081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	01 Sep 2020 14:16:31
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	System	01 Sep 2020 14:16:31

**US3242081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	08 Sep 2020 15:10:12
	(b) (4)	

US3242081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
	(b) (4), (b) (6)	
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		02 Nov 2020 08:06:41
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Could not get into contact with subject until 9/8, two days out of study window' (Site from System).	Grace Newville (b) (4)	08 Sep 2020 15:10:34
	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Sep 2020 15:10:12
User entered '8 Sep 2020'	Grace Newville (b) (4)	08 Sep 2020 15:10:12
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	08 Sep 2020 15:10:12
	(b) (4)	



US3242081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered empty.	Grace Newville (b) (4)	08 Sep 2020 15:10:12
	(b) (4)	

US3242081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Grace Newville (b) (4)	08 Sep 2020 15:10:46
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 15:10:46
	System	

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:04

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:04

US3242081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:04

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'VISIT2'	System	11 Sep 2020 20:49:04

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40



US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '15:23'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '11 Sep 2020 15:23'	(b) (4), (b) (6)	11 Sep 2020 22:04:40
	System	

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '98.0' F	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '70'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40



**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'bpm'	System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '12'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '120'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '64'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40



US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '17:14'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '11 Sep 2020 17:14'	(b) (4), (b) (6)	11 Sep 2020 22:04:40
	System	

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '97.4' F	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '72'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40



**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'bpm'	System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '14'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '128'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '70'	Donna Toepfer (b) (4)	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:04:40

US3242081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:15



US3242081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:49:15

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '16:44'	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '11 Sep 2020 16:44'	(b) (4), (b) (6)	11 Sep 2020 20:48:53
	System	



US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'ONCE'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:29

US3242081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:29

US3242081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '16:19'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:29

US3242081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '11 Sep 2020 16:19'	(b) (4), (b) (6)	11 Sep 2020 20:49:29
	System	

US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48



US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '16:15'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '11 Sep 2020 16:15'	(b) (4), (b) (6)	11 Sep 2020 20:49:48
	System	

US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

US3242081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:51**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:49:48

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:49:48
	System	



US3242081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:49:54

**US3242081**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 20:49:54

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:27:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f4f24a8c-c425-40ec-ba14-465f6f1a535d'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	11 Sep 2020 21:21:33

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:27:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f4f24a8c-c425-40ec-ba14-465f6f1a535d' User entered '97.7'	(b) (4), (b) (6) System	11 Sep 2020 21:21:33
	System	11 Sep 2020 21:21:33

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:28:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f4f24a8c-c425-40ec-ba14-465f6f1a535d' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 21:21:33
	System	11 Sep 2020 21:21:33

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:28:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f4f24a8c-c425-40ec-ba14-465f6f1a535d' User entered '11 Sep 2020 17:28'	(b) (4), (b) (6) System	11 Sep 2020 21:21:33
	System	11 Sep 2020 21:21:33

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 17:04'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 19:34'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:16:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '47cbff23-f4bc-484e-a5ab-4dd905d5eefb' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 02:10:45
	System	12 Sep 2020 02:10:45

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:17:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '47cbff23-f4bc-484e-a5ab-4dd905d5eefb' User entered '98.1'	(b) (4), (b) (6) System	12 Sep 2020 02:10:45
	System	12 Sep 2020 02:10:45

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:17:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '47cbff23-f4bc-484e-a5ab-4dd905d5eefb' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:10:45
	System	12 Sep 2020 02:10:45

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:17:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '47cbff23-f4bc-484e-a5ab-4dd905d5eefb' User entered '11 Sep 2020 22:17'	(b) (4), (b) (6) System	12 Sep 2020 02:10:45
	System	12 Sep 2020 02:10:45

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 20:29'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 2'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:27:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5bbd1829-ee3a-4296-869f-1c636972cccd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Sep 2020 05:21:00
	System	13 Sep 2020 05:21:00

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:27:40', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5bbd1829-ee3a-4296-869f-1c636972cccd' User entered '98.0'	(b) (4), (b) (6) System	13 Sep 2020 05:21:00
	System	13 Sep 2020 05:21:00

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:27:47', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5bbd1829-ee3a-4296-869f-1c636972cccd' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 05:21:00
	System	13 Sep 2020 05:21:00

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:27:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5bbd1829-ee3a-4296-869f-1c636972cccd' User entered '13 Sep 2020 01:27'	(b) (4), (b) (6) System	13 Sep 2020 05:21:00
	System	13 Sep 2020 05:21:00

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 3'	System	11 Sep 2020 20:48:53



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:19:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '794a25b4-85c3-49b5-9dfc-b7c70abdf3f3'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	14 Sep 2020 06:13:08
	System	14 Sep 2020 06:13:08

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:19:46', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '794a25b4-85c3-49b5-9dfc-b7c70abdf3f3' User entered '97.7'	(b) (4), (b) (6) System	14 Sep 2020 06:13:08
	System	14 Sep 2020 06:13:08

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:19:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '794a25b4-85c3-49b5-9dfc-b7c70abdf3f3'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Sep 2020 06:13:08

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '794a25b4-85c3-49b5-9dfc-b7c70abdf3f3'	(b) (4), (b) (6)	
	System	14 Sep 2020 06:13:08
User entered '14 Sep 2020 02:20'	System	14 Sep 2020 06:13:08

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 4'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:33:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '126f6b53-594c-4d19-9323-410ad4a2629d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 05:27:10
	System	15 Sep 2020 05:27:10



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:33:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '126f6b53-594c-4d19-9323-410ad4a2629d' User entered '97.7'	(b) (4), (b) (6) System	15 Sep 2020 05:27:10
	System	15 Sep 2020 05:27:10

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:33:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '126f6b53-594c-4d19-9323-410ad4a2629d' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 05:27:10
	System	15 Sep 2020 05:27:10

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:06', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '126f6b53-594c-4d19-9323-410ad4a2629d' User entered '15 Sep 2020 01:34'	(b) (4), (b) (6) System	15 Sep 2020 05:27:10
	System	15 Sep 2020 05:27:10

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 5'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:02:45', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'bbb0c745-a8a2-443e-9fc9-523bcf59bc20' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 01:56:11
	System	16 Sep 2020 01:56:11

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:02:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'bbb0c745-a8a2-443e-9fc9-523bcf59bc20' User entered '97.7'	(b) (4), (b) (6) System	16 Sep 2020 01:56:11
	System	16 Sep 2020 01:56:11



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:02:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'bbb0c745-a8a2-443e-9fc9-523bcf59bc20'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 01:56:11

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:06', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'bbb0c745-a8a2-443e-9fc9-523bcf59bc20' User entered '15 Sep 2020 22:03'	(b) (4), (b) (6) System	16 Sep 2020 01:56:11
	System	16 Sep 2020 01:56:11

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 6'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '64ef9cee-2848-4678-a6ca-3bffc89f8364' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Sep 2020 03:00:40
	System	17 Sep 2020 03:00:40

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '64ef9cee-2848-4678-a6ca-3bffc89f8364' User entered '97.3'	(b) (4), (b) (6) System	17 Sep 2020 03:00:40
	System	17 Sep 2020 03:00:40

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '64ef9cee-2848-4678-a6ca-3bffc89f8364'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 03:00:40



US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '64ef9cee-2848-4678-a6ca-3bffc89f8364' User entered '16 Sep 2020 23:07'	(b) (4), (b) (6) System	17 Sep 2020 03:00:40
	System	17 Sep 2020 03:00:40

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
Data entry locked.	(b) (4), (b) (6)	
	System	11 Sep 2020 20:48:53
User entered 'Day 7'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1e31146-b7d1-41eb-ad06-d0ba9a275780' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Sep 2020 05:14:48
	System	18 Sep 2020 05:14:48

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1e31146-b7d1-41eb-ad06-d0ba9a275780' User entered '98.0'	(b) (4), (b) (6) System	18 Sep 2020 05:14:48
	System	18 Sep 2020 05:14:48

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1e31146-b7d1-41eb-ad06-d0ba9a275780' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 05:14:48
	System	18 Sep 2020 05:14:48

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:45', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c1e31146-b7d1-41eb-ad06-d0ba9a275780' User entered '18 Sep 2020 01:21'	(b) (4), (b) (6) System	18 Sep 2020 05:14:48
	System	18 Sep 2020 05:14:48



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:28:58', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '80c0570b-274d-4a2e-a99d-b17b4cffd5b2'	(b) (4), (b) (6)	
	System	11 Sep 2020 21:22:41
User entered 'None (1)'	System	11 Sep 2020 21:22:41

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '80c0570b-274d-4a2e-a99d-b17b4cffd5b2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Sep 2020 21:22:41

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:13', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '80c0570b-274d-4a2e-a99d-b17b4cffd5b2' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 21:22:41
	System	11 Sep 2020 21:22:41

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '80c0570b-274d-4a2e-a99d-b17b4cffd5b2'	(b) (4), (b) (6)	
	System	11 Sep 2020 21:22:41
User entered 'None (1)'	System	11 Sep 2020 21:22:41

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '80c0570b-274d-4a2e-a99d-b17b4cffd5b2' User entered '11 Sep 2020 17:29'	(b) (4), (b) (6) System	11 Sep 2020 21:22:41
	System	11 Sep 2020 21:22:41



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 17:04'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 19:34'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:17:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09491d72-f325-43ca-acc0-4b117595b260' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 02:12:13
	System	12 Sep 2020 02:12:13

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:18:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09491d72-f325-43ca-acc0-4b117595b260' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:12:13
	System	12 Sep 2020 02:12:13

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:18:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09491d72-f325-43ca-acc0-4b117595b260' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:12:13
	System	12 Sep 2020 02:12:13

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:18:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09491d72-f325-43ca-acc0-4b117595b260' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 02:12:13
	System	12 Sep 2020 02:12:13

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:19:02', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09491d72-f325-43ca-acc0-4b117595b260' User entered '11 Sep 2020 22:19'	(b) (4), (b) (6) System	12 Sep 2020 02:12:13
	System	12 Sep 2020 02:12:13



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 20:29'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 2'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:28:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f0aa1217-a481-4de5-a600-f72bb639771a' User entered 'None (1)'	(b) (4), (b) (6) System	13 Sep 2020 05:22:26
	System	13 Sep 2020 05:22:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:28:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f0aa1217-a481-4de5-a600-f72bb639771a' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 05:22:26
	System	13 Sep 2020 05:22:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:28:55', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f0aa1217-a481-4de5-a600-f72bb639771a' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 05:22:26
	System	13 Sep 2020 05:22:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f0aa1217-a481-4de5-a600-f72bb639771a' User entered 'None (1)'	(b) (4), (b) (6) System	13 Sep 2020 05:22:26
	System	13 Sep 2020 05:22:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f0aa1217-a481-4de5-a600-f72bb639771a' User entered '13 Sep 2020 01:29'	(b) (4), (b) (6) System	13 Sep 2020 05:22:26
	System	13 Sep 2020 05:22:26



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 3'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:18', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b383ffa1-ecce-48d8-bd7c-bc7e230a2498'	(b) (4), (b) (6)	
User entered 'None (1)'	System	14 Sep 2020 06:13:56

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b383ffa1-ecce-48d8-bd7c-bc7e230a2498'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Sep 2020 06:13:56

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b383ffa1-ecce-48d8-bd7c-bc7e230a2498'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Sep 2020 06:13:56

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b383ffa1-ecce-48d8-bd7c-bc7e230a2498'	(b) (4), (b) (6)	
User entered 'None (1)'	System	14 Sep 2020 06:13:56

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:20:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b383ffa1-ecce-48d8-bd7c-bc7e230a2498'	(b) (4), (b) (6)	
User entered '14 Sep 2020 02:20'	System	14 Sep 2020 06:13:56



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 4'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f09d09ab-e6bc-4ae9-8054-ee237d07f5d0'	(b) (4), (b) (6)	
User entered 'None (1)'	System	15 Sep 2020 05:27:47

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:19', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f09d09ab-e6bc-4ae9-8054-ee237d07f5d0' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 05:27:47
	System	15 Sep 2020 05:27:47

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f09d09ab-e6bc-4ae9-8054-ee237d07f5d0' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 05:27:47
	System	15 Sep 2020 05:27:47

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:28', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f09d09ab-e6bc-4ae9-8054-ee237d07f5d0'	(b) (4), (b) (6)	
User entered 'None (1)'	System	15 Sep 2020 05:27:47

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:42', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f09d09ab-e6bc-4ae9-8054-ee237d07f5d0' User entered '15 Sep 2020 01:34'	(b) (4), (b) (6) System	15 Sep 2020 05:27:47
	System	15 Sep 2020 05:27:47



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 5'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:14', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3de76468-a16e-4adb-94f6-05bd4970c2d0' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 01:56:45
	System	16 Sep 2020 01:56:45

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:19', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3de76468-a16e-4adb-94f6-05bd4970c2d0' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:56:45
	System	16 Sep 2020 01:56:45

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3de76468-a16e-4adb-94f6-05bd4970c2d0' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:56:45
	System	16 Sep 2020 01:56:45

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:28', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3de76468-a16e-4adb-94f6-05bd4970c2d0' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 01:56:45
	System	16 Sep 2020 01:56:45

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:42', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '3de76468-a16e-4adb-94f6-05bd4970c2d0' User entered '15 Sep 2020 22:03'	(b) (4), (b) (6) System	16 Sep 2020 01:56:45
	System	16 Sep 2020 01:56:45



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 6'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f36f49ee-f468-48e1-bac4-0481cbe2778d'	(b) (4), (b) (6)	
	System	17 Sep 2020 03:01:22
User entered 'None (1)'	System	17 Sep 2020 03:01:22

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f36f49ee-f468-48e1-bac4-0481cbe2778d' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 03:01:22
	System	17 Sep 2020 03:01:22

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:07:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f36f49ee-f468-48e1-bac4-0481cbe2778d' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 03:01:22
	System	17 Sep 2020 03:01:22

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:02', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f36f49ee-f468-48e1-bac4-0481cbe2778d' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 03:01:22
	System	17 Sep 2020 03:01:22

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f36f49ee-f468-48e1-bac4-0481cbe2778d' User entered '16 Sep 2020 23:08'	(b) (4), (b) (6) System	17 Sep 2020 03:01:22
	System	17 Sep 2020 03:01:22



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 7'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '85729420-aa9f-403f-bfe6-629daaeafa96'	(b) (4), (b) (6)	
User entered 'None (1)'	System	18 Sep 2020 05:15:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:21:58', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '85729420-aa9f-403f-bfe6-629daaeafa96'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 05:15:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '85729420-aa9f-403f-bfe6-629daaeafa96' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 05:15:26
	System	18 Sep 2020 05:15:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '85729420-aa9f-403f-bfe6-629daaeafa96'	(b) (4), (b) (6)	
	System	18 Sep 2020 05:15:26
User entered 'None (1)'	System	18 Sep 2020 05:15:26

US3242081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:24', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '85729420-aa9f-403f-bfe6-629daaeafa96'	(b) (4), (b) (6)	
User entered '18 Sep 2020 01:22'	System	18 Sep 2020 05:15:26



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:29:58', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:30:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:30:09', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:30:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:23:48
	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:30:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Sep 2020 21:23:48

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T17:30:41', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b347d3ff-4642-4eac-94aa-895596badd55'	(b) (4), (b) (6)	
	System	11 Sep 2020 21:23:48
User entered '11 Sep 2020 17:30'	System	11 Sep 2020 21:23:48

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 17:04'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 19:34'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:19:11', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:20:30', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:19:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:19:59', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:20:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:20:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:20:11', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-11T22:21:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '26b64121-e45e-4562-9a62-4e8551fd5eaf' User entered '11 Sep 2020 22:21'	(b) (4), (b) (6) System	12 Sep 2020 02:14:07
	System	12 Sep 2020 02:14:07

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '11 Sep 2020 20:29'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 2'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:29', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:41', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:29:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-13T01:30:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '206bbbec-5d62-4b4a-9517-4a13e5a945fa' User entered '13 Sep 2020 01:30'	(b) (4), (b) (6) System	13 Sep 2020 05:23:15
	System	13 Sep 2020 05:23:15

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 3'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:01', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:16', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:21:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-14T02:22:01', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7e0229a7-55bd-431c-af9d-16d9ddd29287' User entered '14 Sep 2020 02:22'	(b) (4), (b) (6) System	14 Sep 2020 06:15:06
	System	14 Sep 2020 06:15:06

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 4'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:34:58', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:35:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:35:06', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:35:10', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:35:16', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T01:35:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '57c81bf5-4a61-43f4-8a2f-6bd086d34834' User entered '15 Sep 2020 01:35'	(b) (4), (b) (6) System	15 Sep 2020 05:28:40
	System	15 Sep 2020 05:28:40

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 5'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:49', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:03:57', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:04:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:04:08', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:04:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-15T22:04:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '69019ba0-bd60-4dbe-90b5-9eb3d8118d6d' User entered '15 Sep 2020 22:04'	(b) (4), (b) (6) System	16 Sep 2020 01:57:46
	System	16 Sep 2020 01:57:46

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 6'	System	11 Sep 2020 20:48:53

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:25', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:28', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:08:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 03:02:25
	System	17 Sep 2020 03:02:25

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-16T23:09:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '093f3b33-6d99-4c9d-8481-92d3c5151026'	(b) (4), (b) (6)	
User entered '16 Sep 2020 23:09'	System	17 Sep 2020 03:02:25

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:48:53
User entered 'Day 7'	System	11 Sep 2020 20:48:53



US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:40', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:22:55', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

US3242081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:23:01', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-09-18T01:23:17', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '852b5591-bd7f-44e7-ab0c-7e7bfeb76187' User entered '18 Sep 2020 01:23'	(b) (4), (b) (6) System	18 Sep 2020 05:16:19
	System	18 Sep 2020 05:16:19



**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

**US3242081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:51**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:48:53

US3242081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 23:01:43
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '21 Sep 2020'	Grace Newville (b) (4)	21 Sep 2020 23:01:43
	(b) (4)	

US3242081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	21 Sep 2020 23:01:43
	(b) (4)	

US3242081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Grace Newville (b) (4)	21 Sep 2020 23:01:43
	(b) (4)	

US3242081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 23:01:46
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6)	21 Sep 2020 23:01:46
	System	



**US3242081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Grace Newville (b) (4)	25 Sep 2020 15:11:41
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '25 Sep 2020'	Grace Newville (b) (4)	25 Sep 2020 15:11:41
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	25 Sep 2020 15:11:41
	(b) (4)	

US3242081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Grace Newville (b) (4)	25 Sep 2020 15:11:41
	(b) (4)	

US3242081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Grace Newville (b) (4)	25 Sep 2020 15:11:46
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	System	25 Sep 2020 15:11:46

**US3242081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Oct 2020 18:21:30
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '2 Oct 2020'	Erynn McKinley (b) (4)	02 Oct 2020 18:21:30
	(b) (4)	



**US3242081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	02 Oct 2020 18:21:30
	(b) (4)	

US3242081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4)	02 Oct 2020 18:21:30
	(b) (4)	

US3242081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Oct 2020 18:21:33
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6) System	02 Oct 2020 18:21:33

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 19:44:18
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 13 OCT 2020 is reported under UNSCHEDULED visit in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:55:18
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 13 OCT 2020 is reported under UNSCHEDULED visit in PPD Central lab. Else clarify, thank you.' answered with 'This lab should be V3 Day 57 dated 13Oct2020' (Site from DM).	Donna Toepfer (b) (4)	09 Nov 2020 13:43:51
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 13 OCT 2020 is reported under UNSCHEDULED visit in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:11:17
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 13 OCT 2020 is reported under UNSCHEDULED in PPD Central lab. Else clarify, thank you.	(b) (4), (b) (6)	09 Nov 2020 06:11:10
' canceled (Site from DM).		

US3242081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 13 OCT 2020 is reported under UNSCHEDULED in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:10:18
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:56:36
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'DCF submitted, should be Day 57 lab' (Site from DM).	Donna Toepfer (b) (4)	30 Oct 2020 13:06:21
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 23:54:05
User entered '13 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	13 Oct 2020 19:44:18

US3242081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	13 Oct 2020 19:44:18
	(b) (4)	



**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'VISIT3'	System	13 Oct 2020 19:44:18

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '13 Oct 2020'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '14:47'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Oct 2020 14:47'	(b) (4), (b) (6)	13 Oct 2020 19:45:46
	System	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '97.1' F	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	



**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '64'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'bpm'	System	13 Oct 2020 19:45:46

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '16'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Oct 2020 19:45:46

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '114'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Oct 2020 19:45:46

US3242081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '64'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:46
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'mmHg'	(b) (4), (b) (6) System	13 Oct 2020 19:45:46



**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'No (N)'	Erynn McKinley (b) (4)	13 Oct 2020 19:45:50
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:12:51**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered empty.	Erynn McKinley (b) (4)	13 Oct 2020 19:45:50
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 19:46:00
	(b) (4)	

US3242081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '13 Oct 2020'	Erynn McKinley (b) (4)	13 Oct 2020 19:46:00
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered '15:33'	Erynn McKinley (b) (4)	13 Oct 2020 19:46:00
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered '13 Oct 2020 15:33'	(b) (4), (b) (6)	
	System	13 Oct 2020 19:46:00



US3242081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:34:49
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 19:46:02
	(b) (4)	

**US3242081**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	(b) (4), (b) (6) System	13 Oct 2020 19:46:02

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 64'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

[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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-13T15:00:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09dfe188-d6e3-4218-b130-c7d5982a7284' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 18:53:12
	System	13 Oct 2020 18:53:12

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

Have you been exposed to someone with 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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-13T15:00:19', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09dfe188-d6e3-4218-b130-c7d5982a7284'	(b) (4), (b) (6)	
	System	13 Oct 2020 18:53:12
User entered 'No (N)'	System	13 Oct 2020 18:53:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-13T15:00:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '09dfe188-d6e3-4218-b130-c7d5982a7284' User entered '13 Oct 2020 15:00:31'	(b) (4), (b) (6) System	13 Oct 2020 18:53:12
	System	13 Oct 2020 18:53:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 20:21:57



US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 71'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-21T15:14:19', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'fdcf9281-d64e-4464-b757-a6ee8ecbdbc9'	(b) (4), (b) (6)	
	System	21 Oct 2020 19:07:47
User entered 'No (N)'	System	21 Oct 2020 19:07:47

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

Have you been exposed to someone with 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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-21T15:14:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'fdcf9281-d64e-4464-b757-a6ee8ecbdbbe9'	(b) (4), (b) (6)	
	System	21 Oct 2020 19:07:47
User entered 'No (N)'	System	21 Oct 2020 19:07:47

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-21T15:15:13', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'fd9281-d64e-4464-b757-a6ee8ecbde9'	(b) (4), (b) (6)	
	System	21 Oct 2020 19:07:47
User entered '21 Oct 2020 15:15:13'	System	21 Oct 2020 19:07:47

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 78'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

[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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-27T17:59:37', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '107a9737-abc3-491f-9947-4826b9f7d0f9'	(b) (4), (b) (6)	27 Oct 2020 21:52:34
User entered 'No (N)'	System	27 Oct 2020 21:52:34



US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

Have you been exposed to someone with 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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-27T17:59:52', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '107a9737-abc3-491f-9947-4826b9f7d0f9'	(b) (4), (b) (6)	
	System	27 Oct 2020 21:52:34
User entered 'No (N)'	System	27 Oct 2020 21:52:34

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-10-27T18:00:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '107a9737-abc3-491f-9947-4826b9f7d0f9' User entered '27 Oct 2020 18:00:04'	(b) (4), (b) (6) System	27 Oct 2020 21:52:34
	System	27 Oct 2020 21:52:34

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 92'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

[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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-10T08:37:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1ac6d5ed-c834-4106-a67e-daad6ad84227'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Nov 2020 13:30:15

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-10T08:37:49', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1ac6d5ed-c834-4106-a67e-daad6ad84227'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Nov 2020 13:30:15

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-10T08:38:04', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1ac6d5ed-c834-4106-a67e-daad6ad84227' User entered '10 Nov 2020 08:38:04'	(b) (4), (b) (6) System	10 Nov 2020 13:30:15
	System	10 Nov 2020 13:30:15



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered 'Day 99'	System	13 Aug 2020 20:21:57

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-17T17:15:16', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc16c0e7-6fdb-4093-bd78-d5be91982578' User entered 'No (N)'	(b) (4), (b) (6) System	17 Nov 2020 22:07:29
	System	17 Nov 2020 22:07:29

US3242081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

Have you been exposed to someone with 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 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-17T17:15:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc16c0e7-6fdb-4093-bd78-d5be91982578'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Nov 2020 22:07:29

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-17T17:15:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc16c0e7-6fdb-4093-bd78-d5be91982578' User entered '17 Nov 2020 17:15:35'	(b) (4), (b) (6) System	17 Nov 2020 22:07:29
	System	17 Nov 2020 22:07:29

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 20:21:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:08:54
	(b) (4), (b) (6)	
Data entry locked.	System	13 Aug 2020 20:21:57
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 20:21:57



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:34:35

US3242081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:51

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)	23 Dec 2020 21:35:12
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 'per source this was for routine bloodwork' (Site from DM).	Donna Toepfer (b) (4)	18 Dec 2020 14:08:34
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)	18 Dec 2020 11:33:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:12:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9'	System	24 Nov 2020 00:05:23
User entered 'Yes (Y)'	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:12:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9'	System	24 Nov 2020 00:05:23
User entered 'No (N)'	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:12:46', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9' User entered 'No (N)'	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:12:55', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9' User entered 'Yes (Y)'	System	24 Nov 2020 00:05:23
	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Please 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:13:12', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9'	System	24 Nov 2020 00:05:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-23T19:13:31', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '7225e55f-f63d-41ef-b4ed-24ac08a506e9' User entered '23 Nov 2020 19:13:31'	System	24 Nov 2020 00:05:23

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-30T18:54:41', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '305fcdfe-0486-495f-930c-93f3ac9f4fe1'	System	30 Nov 2020 23:47:12
User entered 'Yes (Y)'	System	30 Nov 2020 23:47:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-30T18:54:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '305fcdfe-0486-495f-930c-93f3ac9f4fe1' User entered 'No (N)'	System	30 Nov 2020 23:47:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-30T18:55:06', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '305fcdfe-0486-495f-930c-93f3ac9f4fe1'	System	30 Nov 2020 23:47:12
User entered 'No (N)'	System	30 Nov 2020 23:47:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-30T18:55:19', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '305fcdfe-0486-495f-930c-93f3ac9f4fe1'	System	30 Nov 2020 23:47:12
User entered 'No (N)'	System	30 Nov 2020 23:47:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-11-30T18:55:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '305fcdfe-0486-495f-930c-93f3ac9f4fe1' User entered '30 Nov 2020 18:55:34'	System	30 Nov 2020 23:47:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-07T21:07:53', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e52141a7-2a95-4d86-9dc3-bdee2f184ef3' User entered 'No (N)'	System	08 Dec 2020 01:59:57
	System	08 Dec 2020 01:59:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-07T21:08:07', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e52141a7-2a95-4d86-9dc3-bdee2f184ef3' User entered 'No (N)'	System	08 Dec 2020 01:59:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-07T21:08:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e52141a7-2a95-4d86-9dc3-bdee2f184ef3' User entered '07 Dec 2020 21:08:26'	System	08 Dec 2020 01:59:57
	System	08 Dec 2020 01:59:57

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-12T00:02:14', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '21534f29-32d2-41b3-bf75-e617659241e1' User entered 'No (N)'	System	12 Dec 2020 04:54:04
	System	12 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-12T00:02:28', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '21534f29-32d2-41b3-bf75-e617659241e1' User entered 'No (N)'	System	12 Dec 2020 04:54:04
	System	12 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-12T00:02:38', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '21534f29-32d2-41b3-bf75-e617659241e1' User entered '12 Dec 2020 00:02:38'	System	12 Dec 2020 04:54:04
	System	12 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-19T00:02:46', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0807b8c9-36aa-4a24-a31c-66754adcaa84' User entered 'No (N)'	System	19 Dec 2020 04:54:22
	System	19 Dec 2020 04:54:22

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-19T00:02:56', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0807b8c9-36aa-4a24-a31c-66754adcaa84' User entered 'No (N)'	System	19 Dec 2020 04:54:22
	System	19 Dec 2020 04:54:22



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-19T00:03:06', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0807b8c9-36aa-4a24-a31c-66754adcaa84' User entered '19 Dec 2020 00:03:06'	System	19 Dec 2020 04:54:22
	System	19 Dec 2020 04:54:22

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-26T00:02:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e19e71d7-f13f-4d93-ad81-2c1d531cab26'	System	26 Dec 2020 04:54:04
User entered 'No (N)'	System	26 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-26T00:02:43', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e19e71d7-f13f-4d93-ad81-2c1d531cab26'	System	26 Dec 2020 04:54:04
User entered 'No (N)'	System	26 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2020-12-26T00:02:54', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'e19e71d7-f13f-4d93-ad81-2c1d531cab26' User entered '26 Dec 2020 00:02:54'	System	26 Dec 2020 04:54:04
	System	26 Dec 2020 04:54:04

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-02T00:03:27', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b822dbd3-3184-4338-bd6c-79181c384db1'	System	02 Jan 2021 04:54:50
User entered 'No (N)'	System	02 Jan 2021 04:54:50

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-02T00:03:39', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b822dbd3-3184-4338-bd6c-79181c384db1'	System	02 Jan 2021 04:54:50
User entered 'No (N)'	System	02 Jan 2021 04:54:50

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-02T00:03:48', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'b822dbd3-3184-4338-bd6c-79181c384db1'	System	02 Jan 2021 04:54:50
User entered '02 Jan 2021 00:03:48'	System	02 Jan 2021 04:54:50

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-09T01:59:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '88c434ce-dd24-45f6-954c-7c0529737b60'	System	09 Jan 2021 06:50:52
User entered 'No (N)'	System	09 Jan 2021 06:50:52

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-09T01:59:49', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '88c434ce-dd24-45f6-954c-7c0529737b60'	System	09 Jan 2021 06:50:52
User entered 'No (N)'	System	09 Jan 2021 06:50:52

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-09T01:59:59', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '88c434ce-dd24-45f6-954c-7c0529737b60' User entered '09 Jan 2021 01:59:59'	System	09 Jan 2021 06:50:52
	System	09 Jan 2021 06:50:52

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-18T10:36:15', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8f0e43d4-bb34-4380-89cb-31ccb859d5a6'	System	18 Jan 2021 15:27:13
User entered 'No (N)'	System	18 Jan 2021 15:27:13

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-18T10:36:26', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8f0e43d4-bb34-4380-89cb-31ccb859d5a6'	System	18 Jan 2021 15:27:13
User entered 'No (N)'	System	18 Jan 2021 15:27:13



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-18T10:36:35', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8f0e43d4-bb34-4380-89cb-31ccb859d5a6' User entered '18 Jan 2021 10:36:35'	System	18 Jan 2021 15:27:13
	System	18 Jan 2021 15:27:13

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-23T02:46:09', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c6011c8f-478d-4a0f-be34-d7a671934c14'	System	23 Jan 2021 07:37:05
User entered 'No (N)'	System	23 Jan 2021 07:37:05

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-23T02:46:23', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c6011c8f-478d-4a0f-be34-d7a671934c14'	System	23 Jan 2021 07:37:05
User entered 'No (N)'	System	23 Jan 2021 07:37:05

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-23T02:46:32', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'c6011c8f-478d-4a0f-be34-d7a671934c14' User entered '23 Jan 2021 02:46:32'	System	23 Jan 2021 07:37:05
	System	23 Jan 2021 07:37:05

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-30T10:17:20', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '92b026d8-c0c3-48ae-be20-7696d53fa93d' User entered 'No (N)'	System	30 Jan 2021 15:08:07

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-30T10:17:34', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '92b026d8-c0c3-48ae-be20-7696d53fa93d' User entered 'No (N)'	System	30 Jan 2021 15:08:07

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-01-30T10:17:40', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '92b026d8-c0c3-48ae-be20-7696d53fa93d' User entered '30 Jan 2021 10:17:40'	System	30 Jan 2021 15:08:07
	System	30 Jan 2021 15:08:07

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-06T01:44:21', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0997dcb2-baa7-402e-8619-cb89d1da7c23' User entered 'No (N)'	System	06 Feb 2021 06:35:16
	System	06 Feb 2021 06:35:16

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-06T01:44:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0997dcb2-baa7-402e-8619-cb89d1da7c23' User entered 'No (N)'	System	06 Feb 2021 06:35:16
	System	06 Feb 2021 06:35:16

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-06T01:45:02', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0997dcb2-baa7-402e-8619-cb89d1da7c23' User entered '06 Feb 2021 01:45:02'	System	06 Feb 2021 06:35:16
	System	06 Feb 2021 06:35:16

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-13T08:27:32', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5231d2bc-4e0a-4ed5-9371-e03e3d45b0df' User entered 'No (N)'	System	13 Feb 2021 13:22:27
	System	13 Feb 2021 13:22:27

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-13T08:27:42', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5231d2bc-4e0a-4ed5-9371-e03e3d45b0df' User entered 'No (N)'	System	13 Feb 2021 13:22:27



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-13T08:27:51', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5231d2bc-4e0a-4ed5-9371-e03e3d45b0df' User entered '13 Feb 2021 08:27:51'	System	13 Feb 2021 13:22:27
	System	13 Feb 2021 13:22:27

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-20T00:50:22', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5508a57b-7d25-4520-aa88-7c4f66e66bee' User entered 'No (N)'	System	20 Feb 2021 05:45:12
	System	20 Feb 2021 05:45:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-20T00:50:33', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5508a57b-7d25-4520-aa88-7c4f66e66bee' User entered 'No (N)'	System	20 Feb 2021 05:45:12
	System	20 Feb 2021 05:45:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-20T00:50:44', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '5508a57b-7d25-4520-aa88-7c4f66e66bee' User entered '20 Feb 2021 00:50:44'	System	20 Feb 2021 05:45:12
	System	20 Feb 2021 05:45:12

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-27T00:35:50', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0496895f-5316-4b81-b67e-44b42937df74' User entered 'No (N)'	System	27 Feb 2021 05:30:43
	System	27 Feb 2021 05:30:43

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-27T00:36:03', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0496895f-5316-4b81-b67e-44b42937df74' User entered 'No (N)'	System	27 Feb 2021 05:30:43
	System	27 Feb 2021 05:30:43

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-02-27T00:36:21', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0496895f-5316-4b81-b67e-44b42937df74'	System	27 Feb 2021 05:30:43
User entered '27 Feb 2021 00:36:21'	System	27 Feb 2021 05:30:43

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:34:35



**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-08T19:57:07-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc587b1a-4f9b-4c1e-94a1-7b76a8e7f65e'	System	09 Mar 2021 00:51:39
User entered 'No (N)'	System	09 Mar 2021 00:51:39

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-08T19:57:19-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc587b1a-4f9b-4c1e-94a1-7b76a8e7f65e'	System	09 Mar 2021 00:51:39
User entered 'No (N)'	System	09 Mar 2021 00:51:39

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-08T19:57:30-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'cc587b1a-4f9b-4c1e-94a1-7b76a8e7f65e' User entered '08 Mar 2021 19:57:30'	System	09 Mar 2021 00:51:39
	System	09 Mar 2021 00:51:39

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-13T00:03:51-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f46b07d7-0f66-48ea-8d5d-b1b19a904ce9'	System	13 Mar 2021 04:58:14
User entered 'No (N)'	System	13 Mar 2021 04:58:14

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-13T00:04:02-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f46b07d7-0f66-48ea-8d5d-b1b19a904ce9'	System	13 Mar 2021 04:58:14
User entered 'No (N)'	System	13 Mar 2021 04:58:14



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-13T00:04:08-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'f46b07d7-0f66-48ea-8d5d-b1b19a904ce9'	System	13 Mar 2021 04:58:14
User entered '13 Mar 2021 00:04:08'	System	13 Mar 2021 04:58:14

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-20T01:46:57-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '558a84e7-9234-4dc4-aa46-ae304e18188b' User entered 'No (N)'	System	20 Mar 2021 05:41:20
	System	20 Mar 2021 05:41:20

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-20T01:47:05-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '558a84e7-9234-4dc4-aa46-ae304e18188b'	System	20 Mar 2021 05:41:20
User entered 'No (N)'	System	20 Mar 2021 05:41:20

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-20T01:47:19-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '558a84e7-9234-4dc4-aa46-ae304e18188b' User entered '20 Mar 2021 01:47:19'	System	20 Mar 2021 05:41:20
	System	20 Mar 2021 05:41:20

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:39:07-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered 'Yes (Y)'	System	27 Mar 2021 12:34:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:39:19-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered 'No (N)'	System	27 Mar 2021 12:34:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:39:31-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered 'No (N)'	System	27 Mar 2021 12:34:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:39:43-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered 'Yes (Y)'	System	27 Mar 2021 12:34:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Please 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:39:56-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Mar 2021 12:34:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-27T08:40:15-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '1d70aae2-447b-4a78-8588-f9bdfd131561'	System	27 Mar 2021 12:34:18
User entered '27 Mar 2021 08:40:15'	System	27 Mar 2021 12:34:18



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:34:12-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b' User entered 'Yes (Y)'	System	03 Apr 2021 16:29:12
	System	03 Apr 2021 16:29:12

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:34:22-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b' User entered 'No (N)'	System	03 Apr 2021 16:29:12
	System	03 Apr 2021 16:29:12

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:34:37-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b' User entered 'No (N)'	System	03 Apr 2021 16:29:12
	System	03 Apr 2021 16:29:12

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:34:51-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b'	System	03 Apr 2021 16:29:12
User entered 'Yes (Y)'	System	03 Apr 2021 16:29:12

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Please 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:35:07-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b'	System	03 Apr 2021 16:29:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 16:29:12



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-03T12:35:24-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '0a51b365-7e44-4930-a385-f47b08ee648b' User entered '03 Apr 2021 12:35:24'	System	03 Apr 2021 16:29:12
	System	03 Apr 2021 16:29:12

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:11:25-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d' User entered 'Yes (Y)'	System	10 Apr 2021 18:05:57
	System	10 Apr 2021 18:05:57

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:11:32-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d' User entered 'No (N)'	System	10 Apr 2021 18:05:57

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:11:39-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d' User entered 'No (N)'	System	10 Apr 2021 18:05:57
	System	10 Apr 2021 18:05:57

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:11:46-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d' User entered 'Yes (Y)'	System	10 Apr 2021 18:05:57
	System	10 Apr 2021 18:05:57



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Please 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:11:58-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d'	System	10 Apr 2021 18:05:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 18:05:57

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-10T14:12:15-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '87b04cc9-7ed6-4b2d-ac49-702a4b166e9d' User entered '10 Apr 2021 14:12:15'	System	10 Apr 2021 18:05:57

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-17T00:03:06-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '02a4582a-838c-4dda-b499-026717bb03d6'	System	17 Apr 2021 03:57:02
User entered 'No (N)'	System	17 Apr 2021 03:57:02

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-17T00:03:17-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '02a4582a-838c-4dda-b499-026717bb03d6'	System	17 Apr 2021 03:57:02
User entered 'No (N)'	System	17 Apr 2021 03:57:02

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-17T00:03:34-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '02a4582a-838c-4dda-b499-026717bb03d6'	System	17 Apr 2021 03:57:02
User entered '17 Apr 2021 00:03:34'	System	17 Apr 2021 03:57:02



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-24T02:17:30-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'dbbfd1f7-2df9-4cd3-8ac2-ae4e483d630c'	System	24 Apr 2021 06:11:18
User entered 'No (N)'	System	24 Apr 2021 06:11:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-24T02:17:47-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'dbbfd1f7-2df9-4cd3-8ac2-ae4e483d630c'	System	24 Apr 2021 06:11:18
User entered 'No (N)'	System	24 Apr 2021 06:11:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-04-24T02:17:56-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: 'dbbfd1f7-2df9-4cd3-8ac2-ae4e483d630c'	System	24 Apr 2021 06:11:18
User entered '24 Apr 2021 02:17:56'	System	24 Apr 2021 06:11:18

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-05-03T16:42:31-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '890424ba-db28-4888-8cc9-269378f65688'	System	03 May 2021 20:36:04
User entered 'No (N)'	System	03 May 2021 20:36:04

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Have you been exposed to someone with 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 (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-05-03T16:42:44-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '890424ba-db28-4888-8cc9-269378f65688'	System	03 May 2021 20:36:04
User entered 'No (N)'	System	03 May 2021 20:36:04

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-05-03T16:42:52-04:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '890424ba-db28-4888-8cc9-269378f65688'	System	03 May 2021 20:36:04
User entered '03 May 2021 16:42:52'	System	03 May 2021 20:36:04

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:34:35



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:34:35



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:34:35



**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:34:35

**US3242081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:34:35
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:34:35

US3242081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:12:51

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 11:26:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-08T19:56:27-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8bb412ce-a657-400f-b467-71f1a2a68b4e'	System	09 Mar 2021 00:50:53
User entered 'No (N)'	System	09 Mar 2021 00:50:53

**US3242081**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:26:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CD8C875-0152-473C-A9AF-0A1D8FA0C88F)', Time: '2021-03-08T19:56:43-05:00', User OID: 'PatientReportedOutcome (US3242081)', ODM File OID: '8bb412ce-a657-400f-b467-71f1a2a68b4e' User entered '08 Mar 2021 19:56:43'	System	09 Mar 2021 00:50:53
	System	09 Mar 2021 00:50:53

**US3242081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Nov 2020 20:36:55
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '5 Nov 2020'	Erynn McKinley (b) (4)	30 Nov 2020 20:36:55
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	30 Nov 2020 20:36:55
	(b) (4)	

US3242081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4)	30 Nov 2020 20:36:55
	(b) (4)	



US3242081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	30 Nov 2020 20:36:59
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:58:24
User entered 'I'	System	30 Nov 2020 20:36:59

**US3242081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Dec 2020 19:15:26
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '9 Dec 2020'	Erynn McKinley (b) (4)	09 Dec 2020 19:15:26
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	09 Dec 2020 19:15:26
	(b) (4)	

US3242081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4)	09 Dec 2020 19:15:26
	(b) (4)	

US3242081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:58:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Dec 2020 19:15:29
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:58:34
User entered 'I'	(b) (4), (b) (6) System	09 Dec 2020 19:15:29



**US3242081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 19:53:23
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	12 Jan 2021 19:53:23
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	12 Jan 2021 19:53:23
	(b) (4)	

US3242081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4)	12 Jan 2021 19:53:23
	(b) (4)	

US3242081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	12 Jan 2021 19:53:26
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered 'I'	(b) (4), (b) (6) System	12 Jan 2021 19:53:26

**US3242081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 17:27:15
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '8 Feb 2021'	Erynn McKinley (b) (4)	08 Feb 2021 17:27:15
	(b) (4)	



**US3242081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	08 Feb 2021 17:27:15
	(b) (4)	

US3242081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4)	08 Feb 2021 17:27:15
	(b) (4)	

US3242081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 17:27:18
	(b) (4)	

**US3242081**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 17:27:18

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Mar 2021 20:37:02
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered '09 Mar 2021'	Erynn McKinley (b) (4)	09 Mar 2021 20:37:02
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:51

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	09 Mar 2021 20:37:02
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered 'VISIT4'	(b) (4), (b) (6) System	09 Mar 2021 20:37:02



US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:17:08

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	



**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:17:08

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:17:08

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:17:08

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:41:56
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:17:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:17:08

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:51**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:00:31



US3242081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:00:31

US3242081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered 'No (N)'	Erynn McKinley (b) (4)	09 Mar 2021 20:37:08
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:12:51**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered empty.	Erynn McKinley (b) (4)	09 Mar 2021 20:37:08
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Mar 2021 20:38:54
	(b) (4)	

US3242081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered '09 Mar 2021'	Erynn McKinley (b) (4)	09 Mar 2021 20:38:54
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered '15:00'	Erynn McKinley (b) (4)	09 Mar 2021 20:38:54
	(b) (4)	

**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered '09 Mar 2021 15:00'	(b) (4), (b) (6) System	09 Mar 2021 20:38:54

US3242081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:26:29
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Mar 2021 20:38:57
	(b) (4)	



**US3242081**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:00:31
User entered '1'	(b) (4), (b) (6) System	09 Mar 2021 20:38:57

**US3242081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:07:57

**US3242081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:38
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:07:57

**US3242081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:07:57

**US3242081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:07:57

US3242081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:08:03

**US3242081**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 23:08:03

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:26
	(b) (4)	



**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '06 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:26
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:26
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:51**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	06 Jan 2021 22:21:26

US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '06 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 15:58:08
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:54:08

US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:58:08
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:54:08

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '06 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	



US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:21:44

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:02:33
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:02:33
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'No (N)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:44
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 22:21:44

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:51**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 22:21:44

US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:52
	(b) (4)	

US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '06 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:52
	(b) (4)	



**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '15:38'	Erynn McKinley (b) (4)	06 Jan 2021 22:21:52
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '06 Jan 2021 15:38'	(b) (4), (b) (6) System	06 Jan 2021 22:21:52

US3242081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:12:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 22:22:02
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '06 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 22:22:02
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:51**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
User entered '15:35'	Erynn McKinley (b) (4)	06 Jan 2021 22:22:02
	(b) (4)	

**US3242081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:51**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:38:58
User entered '06 Jan 2021 15:35'	(b) (4), (b) (6) System	06 Jan 2021 22:22:02

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 16:12:51**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:57
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Sep 2020 21:35:14
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:00:32

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:47:17



US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Insect bite NOS - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 05:28:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 05:28:45
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 21:37:21
User entered 'Insect bites to left leg'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	12 Sep 2020 16:02:19
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	11 Sep 2020 21:36:41
User entered '05 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)' reason for change: New Information	Grace Newville (b) (4)	29 Sep 2020 18:34:47
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '18 Sep 2020' reason for change: New Information	Grace Newville (b) (4)	29 Sep 2020 18:34:47
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:47:17
User signature succeeded.	Nathan Segall (b) (4) [REDACTED]	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

US3242081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41



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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'None (NONE)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'I'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Grace Newville (b) (4)	29 Sep 2020 18:34:47
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:36:41



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
User entered '0'	(b) (4), (b) (6) System	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:47:17
User entered '1'	(b) (4), (b) (6) System	11 Sep 2020 21:36:41

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:47:17

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered	System	06 Apr 2021 15:37:21
'USA-US067-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 15:37:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 00:41:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 00:41:42
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 22:38:18
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 22:37:20
Coding entries removed.	Donna Toepfer (b) (4)	19 Apr 2021 22:37:20
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 22:37:20
User entered 'Severe Sepsis' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastrointestinal inflammatory disorders NEC, PT: Enteritis, LLT: Enteritis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 18:09:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 18:09:33
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 18:08:40
User entered 'Enteritis'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered empty.	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered empty.	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Grade 4 (Grade 4)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33



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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'I'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered empty.	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33



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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

US3242081

Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

None

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '1'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 22:40:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33



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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '0'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered empty.	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:25:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 13:25:30
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
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 'updated' (Site from Safety).	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:03:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Not applicable' (Site from Safety).	Donna Toepfer (b) (4)	20 Apr 2021 18:03:31
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 18:02:34
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:02:34
User entered 'SUBJECT DEVELOPED ENTERITIS REQUIRING HOSPITALIZATION. HAS RESOLVED AND SUBJECT HAS BEEN DISCHARGED. MED RECORDS REQUESTED. Records received, updated SAE and AE and conmeds, Records shows negative Covid test.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:02:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:32:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:12:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medication added' (Site from Safety). DataPoint Verified.	Donna Toepfer (b) (4)	19 Apr 2021 22:40:16
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)	16 Apr 2021 03:41:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:36:47
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:36:22
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'subject developed enteritis requiring hospitalization. Has resolved and subject has been discharged. med records requested.'	Donna Toepfer (b) (4)	05 Apr 2021 18:08:33

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:08:33

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:08:33

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 18:08:33



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:46:20

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastrointestinal inflammatory disorders NEC, PT: Enteritis, LLT: Enteritis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:39:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 22:39:38
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 22:39:19
User entered 'Enteritis'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 22:38:24



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Generated On: 09 Jun 2021 16:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

US3242081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

US3242081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'I'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
User entered '0'	(b) (4), (b) (6) System	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:20
User entered '1'	(b) (4), (b) (6) System	19 Apr 2021 22:38:24

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:46:20

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:46:41

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 22:40:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 22:40:34
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 22:40:20
User entered 'Hyponatremia'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31



US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 22:39:31



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'I'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31



**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

US3242081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
User entered '0'	(b) (4), (b) (6) System	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:46:41
User entered '0'	(b) (4), (b) (6) System	19 Apr 2021 22:39:31

**US3242081**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:46:41



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:12:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:57
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:12:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:14:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:14:14
Data point term sent to Coder	System	13 Aug 2020 20:13:45
User entered 'Atenolol'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Hypertension'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '25'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 21:21:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Donna Toepfer (b) (4)	13 Aug 2020 21:28:17
answered with 'correct per protocol' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 20:21:57
User entered 'un UNK 1994'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 20:13:34
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	13 Aug 2020 20:13:34
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 20:13:06
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Aug 2020 20:13:06



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 20:13:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:13:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 20:13:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:16:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 20:16:13
Data point term sent to Coder	System	13 Aug 2020 20:14:47
User entered 'Lisinopril'	Donna Toepfer (b) (4) (b) (4) (b) (4)	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Hypertension'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '2.5'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 21:21:14
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	13 Aug 2020 21:28:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 20:21:57
User entered 'Un UNK 2000'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 20:14:19

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 20:14:19

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Sep 2020 04:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Sep 2020 04:09:47
Data point term sent to Coder	System	11 Sep 2020 21:38:22
User entered 'Solumedrol'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Insect bites to left leg'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '40' reason for change: Data Entry Error	Donna Toepfer (b) (4)	11 Sep 2020 21:38:58
User entered '125'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once (ONCE)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '09 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '09 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 21:38:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 21:38:06

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 21:38:06

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:17:51
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 21:38:06

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:48:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:48:36
Data point term sent to Coder	System	26 Oct 2020 14:05:37
Coding entries removed.	Donna Toepfer (b) (4) (b) (4)	26 Oct 2020 14:05:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:32:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:32:46
Data point term sent to Coder	System	28 Sep 2020 19:32:10
User entered 'Lyrica'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 12:16:31
Query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 14:05:14
User entered 'NEUROPATHY, bilateral feet' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Oct 2020 14:05:07
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). User entered 'Neuropathy'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	25 Oct 2020 18:37:11 28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '150'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'three times daily (TID)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2005'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Sep 2020 19:31:46

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:31:46



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:31:46

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:34:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:34:44
Data point term sent to Coder	System	28 Sep 2020 19:34:14
User entered 'Lipitor'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Hypercholesterolemia'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '40'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2000'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:33:35



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:33:35

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:33:35

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:35:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:35:46
Data point term sent to Coder	System	28 Sep 2020 19:35:16
User entered 'Clopidogrel'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'CAD'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '75'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2012'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:34:31

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:34:31

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:37:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:37:51
Data point term sent to Coder	System	28 Sep 2020 19:36:19
User entered 'Aspirin'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Heart Health'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '81'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 1994'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:35:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:35:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:37:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:37:51
Data point term sent to Coder	System	28 Sep 2020 19:36:21
User entered 'Multi Vitamin'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Vitamin Supplement'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '1000'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2012'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:36:20

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:36:20



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:36:20

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:38:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:38:52
Data point term sent to Coder	System	28 Sep 2020 19:37:23
User entered 'Vitamin B-12'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:28
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Vitamin Supplement'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '1000'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'ug (ug)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2019'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:37:15



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:37:15

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:37:15

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:39:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:39:40
Data point term sent to Coder	System	28 Sep 2020 19:38:26
User entered 'Vitamin D3'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:25:44
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Vitamin Supplement'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '400'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'IU (IU)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'UN UNK 2019'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered '0'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered empty.	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:02:46
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 19:38:05

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 19:38:05

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 22:26:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 22:26:30
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 22:25:20
User entered 'Omeprazole'	Erynn McKinley (b) (4)	06 Jan 2021 22:24:36
	(b) (4)	

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'GERD'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36



US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered '20'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'UN UNK 2015'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered '0'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:30:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 22:24:36

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 22:24:36

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:26:51
Data point term sent to Coder	System	19 Apr 2021 22:43:21
User entered 'NACL'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:43:08



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe Sepsis'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0.9'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Percent'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:08



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:08

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:08

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:08



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:08

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:23:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:23:30
Data point term sent to Coder	System	19 Apr 2021 22:44:21
User entered 'Heparin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe Sepsis'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '5000'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Units'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:43:54



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:54

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:54

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:43:54

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:24:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:24:24
Data point term sent to Coder	System	19 Apr 2021 22:45:22
User entered 'Iopamidol'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe sepsis(prevent)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '75'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mL (mL)'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:44:57

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:44:57

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:44:57

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:44:57

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:26:51
Data point term sent to Coder	System	19 Apr 2021 22:46:23
User entered 'Ondansetron'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe sepsis prevention'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:45:41



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered '4'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'once (ONCE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:45:41

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:45:41

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:45:41

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:45:41

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
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: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:26:51
Data point term sent to Coder	System	19 Apr 2021 22:47:23
User entered 'Piperacillin-Tazobactam'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe sepsis prevention'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '3.375'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'g (g)'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:46:29



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:46:29

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:46:29

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:46:29



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:46:29

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
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: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:26:51
Data point term sent to Coder	System	19 Apr 2021 22:48:24
User entered 'Piperacillin-tazobactam'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Severe sepsis prevention'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '4.5'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:12



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:12

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:12

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:12

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:27:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:27:41
Data point term sent to Coder	System	19 Apr 2021 22:49:24
User entered 'Pregabalin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Severe sepsis prevention'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '150'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'once (ONCE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:12:51**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '02 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:12:51**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '02 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 22:49:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 22:49:48
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 22:49:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 22:48:49
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:48:49

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:49

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:49

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:48:49

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
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: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 09:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:27:42
Data point term sent to Coder	System	19 Apr 2021 22:50:25
User entered 'Sodium Chloride'	Donna Toepfer (b) (4) (b) (4) (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Severe sepsis prevention'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0.9'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Percent'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 22:49:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:49:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:49:32

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 22:49:32

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 18:07:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:07:36
Data point term sent to Coder	System	20 Apr 2021 18:06:42
User entered 'Ciprofloxacin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	20 Apr 2021 18:06:01



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Enteritis'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '500'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:12:51**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '05 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:01

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 18:06:01

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:06:01



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 18:06:01

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:14:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:14:36
Data point term sent to Coder	System	20 Apr 2021 18:06:47
User entered 'Cyanocobalamin'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Severe Sepsis'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '1000'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'ug (ug)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'once daily (QD)'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:06:44



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Oral (ORAL)'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered '03 Apr 2021'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:06:44



**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:06:44

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:06:44

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 18:06:44

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 18:08:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:08:38
Data point term sent to Coder	System	20 Apr 2021 18:07:48
User entered 'Metronidazole'	Donna Toepfer (b) (4) (b) (4) (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:12:51**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Enteritis'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '500'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'mg (mg)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'three times daily (TID)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '03 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25



US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '05 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:12:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Apr 2021 18:07:25

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:12:51**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 18:07:25

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:07:25

**US3242081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:12:51**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 18:07:25

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:12:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:57
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
DataPoint Un-verified.	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:07:33
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:07:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:07:33
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:30:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:03:02
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Aug 2020 20:00:25

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '1 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:08:46

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Chest PA, AP flat, and upright abdominal'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:08:46



US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:08:46

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:08:46

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:09:12

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'CT Abdomen Pelvis with IV contrast only'	Donna Toepfer (b) (4)	20 Apr 2021 18:09:12

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:09:12

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:09:12

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:12:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:09:47

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:12:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'CT chest Pulmonary embolism with contrast'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:09:47



US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	20 Apr 2021 18:09:47

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:12:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:09:47

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:12:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '01 Apr 2021'	Donna Toepfer (b) (4)	20 Apr 2021 18:10:17

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:12:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'XRay, Acute abdominal series with chest'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:10:17

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:12:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:10:17

US3242081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:12:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	20 Apr 2021 18:10:17

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered	System	06 Apr 2021 15:37:21
'USA-US067-2021-MRNA-1273-P301000012'		

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:06
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Jon'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Nathan'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:09
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Finley'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Segall'	System	06 Apr 2021 15:37:21



US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:10
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered '175 Country Club Drive'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '175 country club dr st100a'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Stockbridge'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'GA'	Donna Toepfer (b) (4)	06 Apr 2021 20:24:09

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 14:01:20
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:56:25
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:56:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 13:44:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:13
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered (b) (4)	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '30281'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'US'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:09:44
User entered '2'	System	20 Apr 2021 16:33:31
User entered '1'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered	System	06 Apr 2021 15:37:21
'USA-US067-2021-MRNA-1273-P301000012'		

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:06
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Jon'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Nathan'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:09
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Finley'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Segall'	System	06 Apr 2021 15:37:21



US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:10
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered '175 Country Club Drive'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '175 country club dr st100a'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Stockbridge'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'GA'	Donna Toepfer (b) (4)	06 Apr 2021 20:24:09

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 14:01:20
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:56:25
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:56:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 13:44:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:13
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered (b) (4)	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '30281'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'US'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:09:44
User entered '2'	System	20 Apr 2021 16:33:31
User entered '1'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:12:51**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered '06/Apr/2021 11:38'	System	06 Apr 2021 15:38:51

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:12:51

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 15:38:51



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered	System	06 Apr 2021 15:37:21
'USA-US067-2021-MRNA-1273-P301000012'		

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21



US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:06
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Jon'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Nathan'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:09
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Finley'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Segall'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:10
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered '175 Country Club Drive'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '175 country club dr st100a'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Stockbridge'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'GA'	Donna Toepfer (b) (4)	06 Apr 2021 20:24:09

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 14:01:20
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:56:25
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:56:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 13:44:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:13
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered (b) (4)	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '30281'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'US'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:09:44
User entered '2'	System	20 Apr 2021 16:33:31
User entered '1'	System	06 Apr 2021 15:38:51



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:12:51**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered '20/Apr/2021 12:33'	System	20 Apr 2021 16:33:31

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:12:51

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 16:33:31

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered	System	06 Apr 2021 15:37:21
'USA-US067-2021-MRNA-1273-P301000012'		

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Yes (Y)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'No (N)'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:06
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Jon'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Nathan'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:09
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered 'Finley'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Segall'	System	06 Apr 2021 15:37:21

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:10
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Apr 2021 16:33:31
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered '175 Country Club Drive'	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '175 country club dr st100a'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered 'Stockbridge'	System	06 Apr 2021 15:37:21

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'GA'	Donna Toepfer (b) (4)	06 Apr 2021 20:24:09

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	03 May 2021 14:11:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 14:01:20
Signature has been broken.	Donna Toepfer (b) (4)	03 May 2021 13:56:25
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 May 2021 13:56:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 May 2021 13:44:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:13
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:45
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Apr 2021 16:33:31
Signature has been broken.	System	20 Apr 2021 16:33:31
User entered (b) (4)	System	20 Apr 2021 16:33:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 15:38:10
User entered '30281'	System	06 Apr 2021 15:37:21



**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 16:32:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:09
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:16:18
User entered 'US'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:51**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 13:09:44
User entered '2'	System	20 Apr 2021 16:33:31
User entered '1'	System	06 Apr 2021 15:38:51

**US3242081**

**Folder: SAE USA-US067-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:12:51**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:36:35
	(b) (4)	
User entered '21/Apr/2021 06:09'	System	21 Apr 2021 13:09:44

US3242081

Folder: SAE USA-US067-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:12:51

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:00:20
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:36:35
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 13:09:44