

US3242258 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:09:30

All time stamps listed in this document are displayed in GMT

US3242258

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

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Participant ID

US3242258

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

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US3242258

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	31 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	SCRN
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US3242258

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3242258

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	COLON CANCER
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	POSTMENOPAUSAL
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)	_____

US3242258

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	COLON SURGERY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	DRUG ALLERGY-LISINOPRIL
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	CHRONIC BRONCHITIS
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 (7)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	CHRONIC OBSTRUCTIVE PULMONARY 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 (8)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

US3242258

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Condition	CHRONIC ASTHMA
Start date (dd MMM yyyy)	01 JAN 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242258

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:27
Height (xxx.x)	67 in
Weight (xxx.x)	164 lb
BMI (xxx.x)	25.73974 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) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Date of assessment (dd MMM yyyy) 31 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

**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**

RETIRED, SHOPS IN  
COMMUNITY AND ATTENDS  
CHURCH

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

**No Risk Identified** False

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

20 of 1912

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:19:44

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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) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	31 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) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 189156

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) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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)	31 AUG 2020
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:42
Temperature (xxx.x)	97.0 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)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 15:04
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 14:34 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 14:34

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) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 31 AUG 2020

Collection time (00:00-23:59) 14:24 (24 HR)

Collection date and time (derived) 31 AUG 2020 14:24

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	31 AUG 2020 14:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**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

31 AUG 2020 15:09

PC Open Date & Time

31 AUG 2020 14:54

PC Close Date & Time

31 AUG 2020 17:24

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	31 AUG 2020 20:25
PC Open Date & Time	31 AUG 2020 18:19
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**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

02 SEP 2020 21:15

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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**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

95.9 °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

03 SEP 2020 20:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

04 SEP 2020 20:10

---

PC Open Date & Time

04 SEP 2020 12:00

---

PC Close Date & Time

05 SEP 2020 11:59

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US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:38

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

---

**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

98.7 °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

06 SEP 2020 19:38

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**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

31 AUG 2020 15:10

PC Open Date & Time

31 AUG 2020 14:54

PC Close Date & Time

31 AUG 2020 17:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**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

31 AUG 2020 20:26

PC Open Date & Time

31 AUG 2020 18:19

PC Close Date & Time

01 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**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

01 SEP 2020 19:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**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

02 SEP 2020 21:15

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**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

03 SEP 2020 20:28

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**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

04 SEP 2020 20:11

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**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

05 SEP 2020 19:39

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**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

06 SEP 2020 19:39

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**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 ☐

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 15:05
PC Open Date & Time	31 AUG 2020 14:54
PC Close Date & Time	31 AUG 2020 17:24

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**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 ☐

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 20:27
PC Open Date & Time	31 AUG 2020 18:19
PC Close Date & Time	01 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**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 ☒

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:45
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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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US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**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 ☒

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:29
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

58 of 1912

EAB) (1725)

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

60 of 1912

EAB) (1725)

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:40
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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 ☒

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:40
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp 07 SEP 2020 20:19

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 20:20
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3242258

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242258

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3242258

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 17:22:50

Generated On: 11 Aug 2021 22:09:30

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 \_\_\_\_\_

US3242258

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 17:22:50

Generated On: 11 Aug 2021 22:09:30

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 \_\_\_\_\_

US3242258

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 17:22:50

Generated On: 11 Aug 2021 22:09:30

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 \_\_\_\_\_

US3242258

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	9 NOV 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
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US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 NOV 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 13:22
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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.*

US3242258

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

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

Collection date (dd MMM yyyy)	9 NOV 2020
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Collection time (00:00-23:59)	13:54 (24 HR)
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Collection date and time (derived)	9 NOV 2020 13:54
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US3242258

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:44

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

09 NOV 2020 14:02:31

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 11:18:54
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 20:16:20
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 19:02:28
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 14:41:06
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 10:32:49

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 18:44:23

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 11:58:52
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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	01 JAN 2021 13:01:43
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 12:06:06
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

15 JAN 2021 20:29:51

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

22 JAN 2021 12:42:32

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 18:35:18
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

07 FEB 2021 07:59:14

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 15:48:37
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

19 FEB 2021 20:17:58

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 18:31:33
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 12:08:18
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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	12 MAR 2021 17:54:00
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 13:59:28
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

26 MAR 2021 14:38:18

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

02 APR 2021 20:23:10

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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

08 APR 2021 13:19:47

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 21:10:06

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 19:57:06
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 20:06:42

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 257

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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°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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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°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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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°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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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°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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59
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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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°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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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 <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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Open Date & Time](#)

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10 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 AUG 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**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 ☐

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3242258

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:09:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 18:32:01

US3242258

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:58:14

Generated On: 11 Aug 2021 22:09:30

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) \_\_\_\_\_

US3242258

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

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.*

US3242258

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 14:09 (24 HR)

Collection date and time (derived) 25 MAR 2021 14:09

US3242258

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 01:18:40

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 01:18:40

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3242258**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:09:30**

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*

**US3242258**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242258

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:09:30

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"/>

**US3242258**

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

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

**Generated On: 11 Aug 2021 22:09:30**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3242258

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 14 JAN 2021

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

Folder OID UNBLND\_DECIDE

US3242258

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 16:06:56

Generated On: 11 Aug 2021 22:09:30

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3242258

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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

US3242258

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:19
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3242258

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:39
Temperature (xxx.x)	97.6 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)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3242258

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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.*

US3242258

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 12:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3242258

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 14 JAN 2021

Collection time (00:00-23:59) 11:09 (24 HR)

Collection date and time (derived) 14 JAN 2021 11:09

US3242258

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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

Collection date (dd MMM yyyy)	14 JAN 2021
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Collection time (00:00 - 23:59)	11:06
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Collection Date and Time (derived)	14 JAN 2021 11:06
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US3242258

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3242258

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	11 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	13:29 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 13:29
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

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)	11 FEB 2021
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 13:29
Temperature (xxx.x)	98.2 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3242258

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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.*

US3242258

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

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 FEB 2021

What was the treatment time? (00:00-23:59) 13:57 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 13:57

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

US3242258

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3242258

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242258

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:07:01

Generated On: 11 Aug 2021 22:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242258

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

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

Visit date (dd MMM yyyy)	25 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

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) \_\_\_\_\_

US3242258

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

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.*

US3242258

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 14:04:03

Generated On: 11 Aug 2021 22:09:30

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 14:09 (24 HR)

Collection date and time (derived) 25 MAR 2021 14:09

US3242258

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	2 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

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

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

AEID

Adverse event

COMMUNITY ACQUIRED  
PNEUMONIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 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)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

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 checked="" 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)	

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

AEID

Adverse event

ASTHMA EXACERBATION

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)

5 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 18:19:42

Generated On: 11 Aug 2021 22:09:30

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 checked="" 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)	_____

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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)	1 JAN 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 (2)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication ZITHROMAX

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication BROM/PSE/DM

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication ZITHROMAX

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication DOXYCYCLINE  
MONOHYDRATE

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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 (8)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication BUDESONIDE / FORMOTEROL  
AEROSOL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 160 / 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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR 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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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 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) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR BONE  
HEALTH

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

	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 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 (13)

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 90

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

If dose unit is Other, specify MCG / 2 PUFFS

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) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 18:19:43

Generated On: 11 Aug 2021 22:09:30

Date of dosing discontinuation (dd MMM yyyy) 5 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:30

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 ☐

Audit

US3242258 (Prod: Clinical Research Atlanta - ERN-PPDS)

**US3242258**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:09:30**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 20:33:42
User entered 'US3242258'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:40:15

US3242258

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:33:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 17:50:40
	(b) (4)	

US3242258

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:33:58
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:40:16

US3242258

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:33:58
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	31 Aug 2020 17:50:40

US3242258

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'SCRN'	System	31 Aug 2020 17:50:40

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:40:17

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '76'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

**US3242258**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:09:30**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'YEARS'	System	31 Aug 2020 18:10:58

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '76'	System	31 Aug 2020 18:11:10

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered 'Female (F)'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered 'I'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:30

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:34:26
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:10:58
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Aug 2020'	System	31 Aug 2020 18:11:10

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2020'	System	31 Aug 2020 18:11:10

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:10
	(b) (4)	

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:40:16

US3242258

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'I'	System	31 Aug 2020 18:11:27

US3242258

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:09:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:27
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:09:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:38:54
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:11:53
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Per source the subject has the following in their medical history: Chronic Bronchitis, Osteopenia and Hyperlipidemia. Please review the source and update accordingly ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:42:00
Query 'Per source the subject has the following in their medical history: Chronic Bronchitis, Osteopenia and Hyperlipidemia. Please review the source and update accordingly ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	17 Nov 2020 02:35:36
User opened query 'Per source the subject has the following in their medical history: Chronic Bronchitis, Osteopenia and Hyperlipidemia. Please review the source and update accordingly ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:06:37
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 20:51:06
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)	31 Aug 2020 18:13:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:13:35
Data point term sent to Coder	System	31 Aug 2020 18:12:52
User entered 'Coronary artery disease'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'Un UNK 2019'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:18
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2019'	System	31 Aug 2020 18:12:18

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2019'	System	31 Aug 2020 18:12:18

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:12:18

US3242258

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:12:18

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer, LLT: Colon cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:13:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:13:34
Data point term sent to Coder	System	31 Aug 2020 18:12:53
User entered 'Colon Cancer'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:12:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2019'	System	31 Aug 2020 18:12:34

**US3242258**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2019'	System	31 Aug 2020 18:12:34

US3242258

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2019'	System	31 Aug 2020 18:12:34

**US3242258**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2019'	System	31 Aug 2020 18:12:34

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:14:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:14:34
Data point term sent to Coder	System	31 Aug 2020 18:13:59
User entered 'Postmenopausal'	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:13:30
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2000'	System	31 Aug 2020 18:13:30

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2000'	System	31 Aug 2020 18:13:30

**US3242258**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:13:30

US3242258

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:13:30

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colon operation, LLT: Colon operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:15:38
Data point term sent to Coder	System	31 Aug 2020 18:15:02
User entered 'Colon Surgery'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:14:59
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2019'	System	31 Aug 2020 18:14:59

**US3242258**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2019'	System	31 Aug 2020 18:14:59

US3242258

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2019'	System	31 Aug 2020 18:14:59

**US3242258**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2019'	System	31 Aug 2020 18:14:59

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:51:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:51:46
Data point term sent to Coder	System	31 Aug 2020 18:16:03
User entered 'Drug allergy-Lisinopril'	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'UN UNK 2012'	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:51:06
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:15:15
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2012'	System	31 Aug 2020 18:15:15

**US3242258**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2012'	System	31 Aug 2020 18:15:15

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:15:15

US3242258

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	31 Aug 2020 18:15:15

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:36:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:36:50
Data point term sent to Coder	System	17 Nov 2020 02:36:41
User entered 'Chronic Bronchitis'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34
	(b) (4)	

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2015'	System	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2015'	System	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:36:34

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:59
Data point term sent to Coder	System	17 Nov 2020 02:37:42
User entered 'Chronic obstructive pulmonary disease'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2015'	System	17 Nov 2020 02:36:52

**US3242258**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2015'	System	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:36:52

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:58
Data point term sent to Coder	System	17 Nov 2020 02:37:42
User entered 'Osteopenia'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Un UNK 2010'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2010'	System	17 Nov 2020 02:37:03

**US3242258**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2010'	System	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:37:03

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:37:58
Data point term sent to Coder	System	17 Nov 2020 02:37:42
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:22
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 2015'	System	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '2015'	System	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:09:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	17 Nov 2020 02:37:13

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma chronic - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 21:00:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 21:00:53
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 20:59:56
User entered 'Chronic Asthma'	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4)	
User entered '01 Jan 1970'	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	(b) (4)	
	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	(b) (4)	
	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '0'	(b) (4)	
	Donna Toepfer (b) (4)	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'Jan 1970'	System	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '1970'	System	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	01 Dec 2020 20:59:30

**US3242258**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered empty.	System	01 Dec 2020 20:59:30

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered '13:27'	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '31 Aug 2020 13:27'	System	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered '67' in	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:11:27

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered '164' lb	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
DataPoint set to visible.	(b) (4) System	31 Aug 2020 18:11:27

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered '25.73974'	System	31 Aug 2020 18:16:47
DataPoint set to visible.	System	31 Aug 2020 18:11:27

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'kg/m2'	System	31 Aug 2020 18:16:47
DataPoint set to visible.	System	31 Aug 2020 18:11:27

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'bpm'	System	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'breaths/min'	System	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'mmHg'	System	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 18:16:47
	(b) (4)	

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User entered 'mmHg'	System	31 Aug 2020 18:16:47

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39

US3242258

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39

US3242258

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:21
	(b) (4)	

US3242258

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:42
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:21
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered 'un UNK 2000'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:30

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:18:57
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:17:41
	(b) (4)	

US3242258

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:30

[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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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[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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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[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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'retired, shops in community and attends church'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Form: Risk of Exposure

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Form: Risk of Exposure

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[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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26

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Form: Risk of Exposure

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**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 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered 'I'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:54:39
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:19:49
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:18:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:21:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:21:29
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:36

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:21:29
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:36
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'VISIT1'	System	31 Aug 2020 18:18:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered '31 AUG 2020'	RWS_ENDPOINT	31 Aug 2020 18:29:27
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered '189156'	RWS_ENDPOINT	31 Aug 2020 18:29:27
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered '>=65 years (3)'	RWS_ENDPOINT	31 Aug 2020 18:29:27
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:50
	(b) (4)	

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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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:30

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:23:27
User entered 'No (N)'	Erynn McKinley (b) (4)	23 Sep 2020 18:50:35
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:46:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:46:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '13:42'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '31 Aug 2020 13:42'	(b) (4), (b) (6)	31 Aug 2020 19:41:59
	System	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '97.0' F	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '64'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'bpm'	System	31 Aug 2020 19:41:59

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '16'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'breaths/min'	(b) (4), (b) (6) System	31 Aug 2020 19:41:59

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '130'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6) System	31 Aug 2020 19:41:59

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '80'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6) System	31 Aug 2020 19:41:59

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '15:04'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '31 Aug 2020 15:04'	(b) (4), (b) (6)	
	System	31 Aug 2020 19:41:59

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '97.5' F	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '68'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'bpm'	System	31 Aug 2020 19:41:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '16'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'breaths/min'	(b) (4), (b) (6)	31 Aug 2020 19:41:59
	System	

US3242258

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '132'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6) System	31 Aug 2020 19:41:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:03
User entered '82'	Donna Toepfer (b) (4)	31 Aug 2020 19:41:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6) System	31 Aug 2020 19:41:59

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:15
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:38:15
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:15
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:38:15
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	31 Aug 2020 18:38:44
	System	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered '14:34'	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '31 Aug 2020 14:34'	(b) (4), (b) (6)	31 Aug 2020 18:38:44
	System	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	31 Aug 2020 18:38:44
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Nov 2020 21:26:35
User entered 'ONCE'	System	31 Aug 2020 18:38:44

US3242258

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:04
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:00
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:04
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:04
User entered '14:24'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:00
	(b) (4)	

**US3242258**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:09:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '31 Aug 2020 14:24'	(b) (4), (b) (6)	31 Aug 2020 18:39:00
	System	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:14
User entered '31 Aug 2020'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:14
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:27:14
User entered '14:15'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '31 Aug 2020 14:15'	(b) (4), (b) (6)	31 Aug 2020 18:39:17
	System	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17
	(b) (4)	

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:27:14
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:27:14
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:39:17

US3242258

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 18:39:17
	System	

US3242258

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:27:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:22

US3242258

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'I'	(b) (4), (b) (6) System	31 Aug 2020 18:39:22

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:09:04', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd2ec5695-b8ca-4a59-b74e-797bba55555d'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	31 Aug 2020 19:18:50

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:09:17', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd2ec5695-b8ca-4a59-b74e-797bba55555d'	(b) (4), (b) (6)	
User entered '97.5'	System	31 Aug 2020 19:18:50

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:09:44', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd2ec5695-b8ca-4a59-b74e-797bba55555d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	31 Aug 2020 19:18:50

**US3242258**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:09:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:09:52', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd2ec5695-b8ca-4a59-b74e-797bba55555d'	(b) (4), (b) (6) System	31 Aug 2020 19:18:50
User entered '31 Aug 2020 15:09'	System	31 Aug 2020 19:18:50

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '31 Aug 2020 14:54'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '31 Aug 2020 17:24'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:25:24', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2f256402-d715-4171-b3a1-25332dbab028'	(b) (4), (b) (6) System	01 Sep 2020 00:26:01
User entered 'Yes (Y)'	System	01 Sep 2020 00:26:01

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:25:31', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2f256402-d715-4171-b3a1-25332dbab028'	(b) (4), (b) (6)	
User entered '97.6'	System	01 Sep 2020 00:26:01

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:25:36', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2f256402-d715-4171-b3a1-25332dbab028'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 00:26:01

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:25:55', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2f256402-d715-4171-b3a1-25332dbab028'	(b) (4), (b) (6) System	01 Sep 2020 00:26:01
User entered '31 Aug 2020 20:25'	System	01 Sep 2020 00:26:01

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '31 Aug 2020 18:19'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 2'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:42:21', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '8e70086d-ce81-48ab-8251-95e463b72576'	(b) (4), (b) (6) System	01 Sep 2020 23:42:54
User entered 'Yes (Y)'	System	01 Sep 2020 23:42:54

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:42:32', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '8e70086d-ce81-48ab-8251-95e463b72576'	(b) (4), (b) (6) System	01 Sep 2020 23:42:54
User entered '98.2'	System	01 Sep 2020 23:42:54

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:42:37', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '8e70086d-ce81-48ab-8251-95e463b72576'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 23:42:54

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:42:49', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '8e70086d-ce81-48ab-8251-95e463b72576'	(b) (4), (b) (6) System	01 Sep 2020 23:42:54
User entered '01 Sep 2020 19:42'	System	01 Sep 2020 23:42:54

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 3'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:14:46', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b8ceb454-23a1-4ab7-bfbe-d21dee1ee8fd'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	03 Sep 2020 01:15:14

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:14:54', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b8ceb454-23a1-4ab7-bfbe-d21dee1ee8fd' User entered '97.7'	(b) (4), (b) (6) System	03 Sep 2020 01:15:14
	System	03 Sep 2020 01:15:14

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:14:59', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b8ceb454-23a1-4ab7-bfbe-d21dee1ee8fd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Sep 2020 01:15:14

**US3242258**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:09:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:11', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b8ceb454-23a1-4ab7-bfbe-d21dee1ee8fd'	(b) (4), (b) (6) System	03 Sep 2020 01:15:14
User entered '02 Sep 2020 21:15'	System	03 Sep 2020 01:15:14

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 4'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:27:30', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '274deb08-b9d3-40b8-b2f1-c9275fb48163'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Sep 2020 00:27:58

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:27:37', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '274deb08-b9d3-40b8-b2f1-c9275fb48163'	(b) (4), (b) (6)	
User entered '95.9'	System	04 Sep 2020 00:27:58

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:27:46', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '274deb08-b9d3-40b8-b2f1-c9275fb48163'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 00:27:58

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:27:55', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '274deb08-b9d3-40b8-b2f1-c9275fb48163'	(b) (4), (b) (6) System	04 Sep 2020 00:27:58
User entered '03 Sep 2020 20:27'	System	04 Sep 2020 00:27:58

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 5'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:06', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a835db3a-bad9-424a-8c4d-75e7064a6f46'	(b) (4), (b) (6) System	05 Sep 2020 00:10:37
User entered 'Yes (Y)'	System	05 Sep 2020 00:10:37

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a835db3a-bad9-424a-8c4d-75e7064a6f46'	(b) (4), (b) (6) System	05 Sep 2020 00:10:37
User entered '98.1'	System	05 Sep 2020 00:10:37

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:19', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a835db3a-bad9-424a-8c4d-75e7064a6f46'	(b) (4), (b) (6)	
	System	05 Sep 2020 00:10:37
User entered 'No (N)'	System	05 Sep 2020 00:10:37

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:32', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a835db3a-bad9-424a-8c4d-75e7064a6f46'	(b) (4), (b) (6) System	05 Sep 2020 00:10:37
User entered '04 Sep 2020 20:10'	System	05 Sep 2020 00:10:37

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 6'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:37:56', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '21a383aa-bf0b-4b60-88ef-a14cddf98132'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	05 Sep 2020 23:38:30

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:07', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '21a383aa-bf0b-4b60-88ef-a14cddf98132'	(b) (4), (b) (6)	
User entered '96.7'	System	05 Sep 2020 23:38:30

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '21a383aa-bf0b-4b60-88ef-a14cddf98132'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 23:38:30

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:25', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '21a383aa-bf0b-4b60-88ef-a14cddf98132'	(b) (4), (b) (6) System	05 Sep 2020 23:38:30
User entered '05 Sep 2020 19:38'	System	05 Sep 2020 23:38:30

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 7'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:37:53', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fecfafaa-3710-4944-9a7d-e8a3ea81b0f4'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	06 Sep 2020 23:38:24

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:37:59', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fecfafa-3710-4944-9a7d-e8a3ea81b0f4'	(b) (4), (b) (6)	
User entered '98.7'	System	06 Sep 2020 23:38:24

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:06', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fecfafaa-3710-4944-9a7d-e8a3ea81b0f4'	(b) (4), (b) (6)	
	System	06 Sep 2020 23:38:24
User entered 'No (N)'	System	06 Sep 2020 23:38:24

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:20', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fecfafa-3710-4944-9a7d-e8a3ea81b0f4'	(b) (4), (b) (6) System	06 Sep 2020 23:38:24
User entered '06 Sep 2020 19:38'	System	06 Sep 2020 23:38:24

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:10:05', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '48482771-055e-44fb-a5c0-288a256fe7c0'	(b) (4), (b) (6) System	31 Aug 2020 19:19:09
User entered 'None (1)'	System	31 Aug 2020 19:19:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:10:25', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '48482771-055e-44fb-a5c0-288a256fe7c0'	(b) (4), (b) (6)	
User entered 'No (N)'	System	31 Aug 2020 19:19:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:10:29', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '48482771-055e-44fb-a5c0-288a256fe7c0'	(b) (4), (b) (6) System	31 Aug 2020 19:19:09
User entered 'No (N)'	System	31 Aug 2020 19:19:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:10:38', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '48482771-055e-44fb-a5c0-288a256fe7c0'	(b) (4), (b) (6)	
	System	31 Aug 2020 19:19:09
User entered 'None (1)'	System	31 Aug 2020 19:19:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:10:45', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '48482771-055e-44fb-a5c0-288a256fe7c0'	(b) (4), (b) (6) System	31 Aug 2020 19:19:09
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 19:19:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 14:54'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 17:24'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:10', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ca505a57-c22d-4519-baf1-3810b28c9cf8'	(b) (4), (b) (6) System	01 Sep 2020 00:26:49
User entered 'None (1)'	System	01 Sep 2020 00:26:49

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:14', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ca505a57-c22d-4519-baf1-3810b28c9cf8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 00:26:49

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:19', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ca505a57-c22d-4519-baf1-3810b28c9cf8'	(b) (4), (b) (6) System	01 Sep 2020 00:26:49
User entered 'No (N)'	System	01 Sep 2020 00:26:49

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:30', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ca505a57-c22d-4519-baf1-3810b28c9cf8'	(b) (4), (b) (6)	
	System	01 Sep 2020 00:26:49
User entered 'None (1)'	System	01 Sep 2020 00:26:49

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ca505a57-c22d-4519-baf1-3810b28c9cf8'	(b) (4), (b) (6) System	01 Sep 2020 00:26:49
User entered '31 Aug 2020 20:26'	System	01 Sep 2020 00:26:49

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 18:19'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 2'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:42:58', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '87547ab8-b30a-4caf-8090-a305b0089b17'	(b) (4), (b) (6)	
	System	01 Sep 2020 23:44:24
User entered 'None (1)'	System	01 Sep 2020 23:44:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:43:34', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '87547ab8-b30a-4caf-8090-a305b0089b17'	(b) (4), (b) (6)	
	System	01 Sep 2020 23:44:24
User entered 'No (N)'	System	01 Sep 2020 23:44:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:43:47', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '87547ab8-b30a-4caf-8090-a305b0089b17'	(b) (4), (b) (6) System	01 Sep 2020 23:44:24
User entered 'No (N)'	System	01 Sep 2020 23:44:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:11', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '87547ab8-b30a-4caf-8090-a305b0089b17'	(b) (4), (b) (6)	
	System	01 Sep 2020 23:44:24
User entered 'None (1)'	System	01 Sep 2020 23:44:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:21', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '87547ab8-b30a-4caf-8090-a305b0089b17'	(b) (4), (b) (6) System	01 Sep 2020 23:44:24
User entered '01 Sep 2020 19:44'	System	01 Sep 2020 23:44:24

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 3'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:30', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2bbb61c5-a84e-4b20-b3ce-1b93c9bcf80d'	(b) (4), (b) (6)	
	System	03 Sep 2020 01:15:59
User entered 'None (1)'	System	03 Sep 2020 01:15:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:34', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2bbb61c5-a84e-4b20-b3ce-1b93c9bcf80d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	03 Sep 2020 01:15:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:38', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2bbb61c5-a84e-4b20-b3ce-1b93c9bcf80d'	(b) (4), (b) (6) System	03 Sep 2020 01:15:59
User entered 'No (N)'	System	03 Sep 2020 01:15:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2bbb61c5-a84e-4b20-b3ce-1b93c9bcf80d'	(b) (4), (b) (6)	
	System	03 Sep 2020 01:15:59
User entered 'None (1)'	System	03 Sep 2020 01:15:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:15:55', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2bbb61c5-a84e-4b20-b3ce-1b93c9bcf80d'	(b) (4), (b) (6) System	03 Sep 2020 01:15:59
User entered '02 Sep 2020 21:15'	System	03 Sep 2020 01:15:59

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 4'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:03', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7b4479b2-c9a1-4bf6-b2fd-83db5417ebc1'	(b) (4), (b) (6)	
	System	04 Sep 2020 00:28:35
User entered 'None (1)'	System	04 Sep 2020 00:28:35

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:08', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7b4479b2-c9a1-4bf6-b2fd-83db5417ebc1'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 00:28:35

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:12', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7b4479b2-c9a1-4bf6-b2fd-83db5417ebc1'	(b) (4), (b) (6) System	04 Sep 2020 00:28:35
User entered 'No (N)'	System	04 Sep 2020 00:28:35

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:20', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7b4479b2-c9a1-4bf6-b2fd-83db5417ebc1'	(b) (4), (b) (6) System	04 Sep 2020 00:28:35
User entered 'None (1)'	System	04 Sep 2020 00:28:35

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:31', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7b4479b2-c9a1-4bf6-b2fd-83db5417ebc1'	(b) (4), (b) (6) System	04 Sep 2020 00:28:35
User entered '03 Sep 2020 20:28'	System	04 Sep 2020 00:28:35

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 5'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:40', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3e7759b0-74b2-4c5c-b77e-5a572237d797'	(b) (4), (b) (6)	
	System	05 Sep 2020 00:11:18
User entered 'None (1)'	System	05 Sep 2020 00:11:18

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:45', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3e7759b0-74b2-4c5c-b77e-5a572237d797'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 00:11:18

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:49', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3e7759b0-74b2-4c5c-b77e-5a572237d797'	(b) (4), (b) (6) System	05 Sep 2020 00:11:18
User entered 'No (N)'	System	05 Sep 2020 00:11:18

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:10:58', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3e7759b0-74b2-4c5c-b77e-5a572237d797'	(b) (4), (b) (6)	
	System	05 Sep 2020 00:11:18
User entered 'None (1)'	System	05 Sep 2020 00:11:18

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3e7759b0-74b2-4c5c-b77e-5a572237d797'	(b) (4), (b) (6) System	05 Sep 2020 00:11:18
User entered '04 Sep 2020 20:11'	System	05 Sep 2020 00:11:18

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 6'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:35', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3174c100-9cc1-47c6-86d1-55b209a4235c'	(b) (4), (b) (6)	
	System	05 Sep 2020 23:39:09
User entered 'None (1)'	System	05 Sep 2020 23:39:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:41', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3174c100-9cc1-47c6-86d1-55b209a4235c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 23:39:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:48', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3174c100-9cc1-47c6-86d1-55b209a4235c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 23:39:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:38:54', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3174c100-9cc1-47c6-86d1-55b209a4235c'	(b) (4), (b) (6)	
	System	05 Sep 2020 23:39:09
User entered 'None (1)'	System	05 Sep 2020 23:39:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:04', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '3174c100-9cc1-47c6-86d1-55b209a4235c'	(b) (4), (b) (6) System	05 Sep 2020 23:39:09
User entered '05 Sep 2020 19:39'	System	05 Sep 2020 23:39:09

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 7'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:28', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fa3bd67a-ab36-42c0-8c2b-74da8f9b84bd'	(b) (4), (b) (6)	
	System	06 Sep 2020 23:39:10
User entered 'None (1)'	System	06 Sep 2020 23:39:10

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:32', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fa3bd67a-ab36-42c0-8c2b-74da8f9b84bd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 23:39:10

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:40', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fa3bd67a-ab36-42c0-8c2b-74da8f9b84bd'	(b) (4), (b) (6) System	06 Sep 2020 23:39:10
User entered 'No (N)'	System	06 Sep 2020 23:39:10

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:38:54', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fa3bd67a-ab36-42c0-8c2b-74da8f9b84bd'	(b) (4), (b) (6)	
	System	06 Sep 2020 23:39:10
User entered 'None (1)'	System	06 Sep 2020 23:39:10

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:06', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fa3bd67a-ab36-42c0-8c2b-74da8f9b84bd'	(b) (4), (b) (6) System	06 Sep 2020 23:39:10
User entered '06 Sep 2020 19:39'	System	06 Sep 2020 23:39:10

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:12', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:23', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:29', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:38', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:04:49', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'None (0)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:05:05', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered 'No (N)'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T15:05:33', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '802fc9ba-6da2-4752-a311-66a6c89173ea'	(b) (4), (b) (6) System	31 Aug 2020 19:08:01
User entered '31 Aug 2020 15:05'	System	31 Aug 2020 19:08:01

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 14:54'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 17:24'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:53', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:26:59', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6) System	01 Sep 2020 00:27:39
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:04', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6) System	01 Sep 2020 00:27:39
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:08', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6) System	01 Sep 2020 00:27:39
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:12', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:16', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6) System	01 Sep 2020 00:27:39
User entered 'None (0)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:22', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-08-31T20:27:32', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1ec59f76-ad72-4b87-9f66-d3cc98148f74'	(b) (4), (b) (6) System	01 Sep 2020 00:27:39
User entered '31 Aug 2020 20:27'	System	01 Sep 2020 00:27:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '31 Aug 2020 18:19'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 2'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:41', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:48', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:54', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:44:59', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:45:04', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6) System	01 Sep 2020 23:45:30
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:45:09', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:45:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-01T19:45:27', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '662cee53-a2e4-4d1f-ae6b-b83ff6046eff'	(b) (4), (b) (6)	
User entered '01 Sep 2020 19:45'	System	01 Sep 2020 23:45:30

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 3'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:04', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered 'None (0)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:22', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6)	
	System	03 Sep 2020 01:17:04
User entered 'No interference with activity (1)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:28', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered 'None (0)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:34', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered 'None (0)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:40', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered 'None (0)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:44', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered 'None (0)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:16:51', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6)	
	System	03 Sep 2020 01:17:04
User entered 'No (N)'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-02T21:17:01', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f663a62-86c8-411a-9af6-47b85b4503b3'	(b) (4), (b) (6) System	03 Sep 2020 01:17:04
User entered '02 Sep 2020 21:17'	System	03 Sep 2020 01:17:04

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 4'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:39', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:50', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:28:56', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:29:02', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:29:07', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6) System	04 Sep 2020 00:29:39
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:29:11', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:29:19', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-03T20:29:36', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'f97560bb-82e4-4d5e-9c3a-1b4dd6e9d3a4'	(b) (4), (b) (6) System	04 Sep 2020 00:29:39
User entered '03 Sep 2020 20:29'	System	04 Sep 2020 00:29:39

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 5'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:24', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:29', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
	System	05 Sep 2020 00:12:20
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:35', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:41', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:47', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:11:53', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6) System	05 Sep 2020 00:12:20
User entered 'None (0)'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:12:03', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Sep 2020 00:12:20

**US3242258**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:09:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-04T20:12:16', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0f29ba6a-805d-4c02-a437-46a4373824ea'	(b) (4), (b) (6) System	05 Sep 2020 00:12:20
User entered '04 Sep 2020 20:12'	System	05 Sep 2020 00:12:20

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 6'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:30', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:37', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:47', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:39:52', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
User entered 'None (0)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:40:01', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6)	
	System	05 Sep 2020 23:40:17
User entered 'No (N)'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-05T19:40:13', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '1afa7a92-1dfd-4e0f-b1f0-2a0342217926'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17
User entered '05 Sep 2020 19:40'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 7'	System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6) System	06 Sep 2020 23:40:16
User entered 'None (0)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:22', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6) System	06 Sep 2020 23:40:16
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:31', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6) System	06 Sep 2020 23:40:16
User entered 'None (0)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:38', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6) System	06 Sep 2020 23:40:16
User entered 'None (0)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:48', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6)	
User entered 'None (0)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:39:58', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-06T19:40:12', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2c04698d-2908-4fb5-8919-2a00ad10f125'	(b) (4), (b) (6) System	06 Sep 2020 23:40:16
User entered '06 Sep 2020 19:40'	System	06 Sep 2020 23:40:16

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 18:38:44

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 23:40:17
User entered 'Day 8'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-07T20:19:46', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7c93db83-289f-49ea-b4d1-133d51970add'	(b) (4), (b) (6) System	08 Sep 2020 00:20:01
User entered 'None (0)'	System	08 Sep 2020 00:20:01

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-07T20:19:56', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7c93db83-289f-49ea-b4d1-133d51970add'	(b) (4), (b) (6) System	08 Sep 2020 00:20:01
User entered '07 Sep 2020 20:19'	System	08 Sep 2020 00:20:01

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
	(b) (4), (b) (6)	
Data entry locked.	System	05 Sep 2020 23:40:17
User entered 'Day 8'	System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-07T20:20:07', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '981242d5-7264-42df-80aa-38917523d6ea'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Sep 2020 00:20:20

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-09-07T20:20:17', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '981242d5-7264-42df-80aa-38917523d6ea'	(b) (4), (b) (6) System	08 Sep 2020 00:20:20
User entered '07 Sep 2020 20:20'	System	08 Sep 2020 00:20:20

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17

US3242258

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:24
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	05 Sep 2020 23:40:17

US3242258

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:11
User entered 'Yes (Y)'	Grace Newville (b) (4)	10 Sep 2020 18:50:02
	(b) (4)	

US3242258

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:11
User entered '10 Sep 2020'	Grace Newville (b) (4)	10 Sep 2020 18:50:02
	(b) (4)	

US3242258

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:11
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	10 Sep 2020 18:50:02
	(b) (4)	

US3242258

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:11
User entered empty.	Grace Newville (b) (4)	10 Sep 2020 18:50:02
	(b) (4)	

US3242258

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:19
User entered 'Yes (Y)'	Grace Newville (b) (4)	10 Sep 2020 18:50:07
	(b) (4)	

US3242258

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 18:50:07
	System	

US3242258

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:52
User entered 'Yes (Y)'	Grace Newville (b) (4)	15 Sep 2020 19:46:50
	(b) (4)	

US3242258

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:52
User entered '15 Sep 2020'	Grace Newville (b) (4)	15 Sep 2020 19:46:50
	(b) (4)	

US3242258

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:52
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	15 Sep 2020 19:46:50
	(b) (4)	

US3242258

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:52
User entered empty.	Grace Newville (b) (4)	15 Sep 2020 19:46:50
	(b) (4)	

US3242258

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:28:59
User entered 'Yes (Y)'	Grace Newville (b) (4)	15 Sep 2020 19:46:44
	(b) (4)	

US3242258

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 19:46:44
	System	

US3242258

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:30:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 15:14:04
	(b) (4)	

US3242258

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:30:22
User entered '24 Sep 2020'	Erynn McKinley (b) (4)	19 Oct 2020 15:14:04
	(b) (4)	

US3242258

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:30:22
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	19 Oct 2020 15:14:04
	(b) (4)	

US3242258

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:30:22
User entered empty.	Erynn McKinley (b) (4)	19 Oct 2020 15:14:04
	(b) (4)	

US3242258

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:30:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 15:14:07
	(b) (4)	

US3242258

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 15:14:07
	System	

US3242258

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Nov 2020 14:44:02

US3242258

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	05 Nov 2020 14:44:02

US3242258

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	05 Nov 2020 14:44:02

US3242258

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'VISIT2'	System	05 Nov 2020 14:44:02

US3242258

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Nov 2020 14:44:08

US3242258

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 14:44:08
	System	

US3242258

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 20:47:40

US3242258

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:40

US3242258

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:40

US3242258

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:40

US3242258

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:08:48
	(b) (4)	

US3242258

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 19:08:48
	System	

US3242258

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 20:47:48

US3242258

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:48

US3242258

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:48

US3242258

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:48

US3242258

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:09:01
	(b) (4)	

US3242258

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	System	09 Nov 2020 19:09:01

US3242258

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 20:47:58

US3242258

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:58

US3242258

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:58

US3242258

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:22:50
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 20:47:58

US3242258

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:09:10
	(b) (4)	

**US3242258**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 19:09:10
	System	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:09:51
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '9 Nov 2020'	Erynn McKinley (b) (4)	09 Nov 2020 19:09:51
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[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 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	09 Nov 2020 19:09:51
	(b) (4)	

**US3242258**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'VISIT3'	System	09 Nov 2020 19:09:51

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '9 Nov 2020'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '13:22'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '9 Nov 2020 13:22'	(b) (4), (b) (6)	09 Nov 2020 19:10:36
	System	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '97.0' F	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '68'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'bpm'	System	09 Nov 2020 19:10:36

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '16'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'breaths/min'	(b) (4), (b) (6)	09 Nov 2020 19:10:36
	System	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '126'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6) System	09 Nov 2020 19:10:36

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '80'	Erynn McKinley (b) (4)	09 Nov 2020 19:10:36
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered 'mmHg'	(b) (4), (b) (6)	09 Nov 2020 19:10:36
	System	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Erynn McKinley (b) (4)	09 Nov 2020 19:11:43
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	09 Nov 2020 19:11:43
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:12:31
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '9 Nov 2020'	Erynn McKinley (b) (4)	09 Nov 2020 19:12:31
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '13:54'	Erynn McKinley (b) (4)	09 Nov 2020 19:12:31
	(b) (4)	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '9 Nov 2020 13:54'	(b) (4), (b) (6)	09 Nov 2020 19:12:31
	System	

US3242258

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Nov 2020 19:12:35
	(b) (4)	

**US3242258**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:50:25
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 19:12:35
	System	

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 64'	System	31 Aug 2020 18:38:44

US3242258

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

US3242258

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 18:38:44

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:05:53
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 18:38:44

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 71'	System	31 Aug 2020 18:38:44

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-09T14:02:13', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fd4368e2-7cc5-458a-8bd4-520230eb6f79'	(b) (4), (b) (6) System	09 Nov 2020 19:02:37
User entered 'No (N)'	System	09 Nov 2020 19:02:37

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-09T14:02:19', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fd4368e2-7cc5-458a-8bd4-520230eb6f79'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Nov 2020 19:02:37

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-09T14:02:31', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'fd4368e2-7cc5-458a-8bd4-520230eb6f79'	(b) (4), (b) (6)	
	System	09 Nov 2020 19:02:37
User entered '09 Nov 2020 14:02:31'	System	09 Nov 2020 19:02:37

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 18:38:44

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 18:38:44

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered 'Day 78'	System	31 Aug 2020 18:38:44

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-14T11:18:27', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd50754e0-5380-4b21-a789-5c27216bde97'	(b) (4), (b) (6) System	14 Nov 2020 16:18:58
User entered 'No (N)'	System	14 Nov 2020 16:18:58

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-14T11:18:38', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd50754e0-5380-4b21-a789-5c27216bde97'	(b) (4), (b) (6)	
	System	14 Nov 2020 16:18:58
User entered 'No (N)'	System	14 Nov 2020 16:18:58

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-14T11:18:54', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd50754e0-5380-4b21-a789-5c27216bde97'	(b) (4), (b) (6)	
User entered '14 Nov 2020 11:18:54'	System	14 Nov 2020 16:18:58
	System	14 Nov 2020 16:18:58

US3242258

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 18:38:44

US3242258

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:26:30
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 18:38:44
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 18:38:44

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-11-21T20:15:46', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '055ddd5-7a6f-493e-8697-6aaacbcac017'	System	22 Nov 2020 01:16:23
User entered 'No (N)'	System	22 Nov 2020 01:16:23

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-11-21T20:15:56', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '055ddd5-7a6f-493e-8697-6aaacbcac017'	System	22 Nov 2020 01:16:23
User entered 'No (N)'	System	22 Nov 2020 01:16:23

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-21T20:16:20', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '055ddd5-7a6f-493e-8697-6aaacbcac017'	System	22 Nov 2020 01:16:23
User entered '21 Nov 2020 20:16:20'	System	22 Nov 2020 01:16:23

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-11-27T19:02:08', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '361a5286-544d-496d-8f31-ca2fe7d9c11f'	System	28 Nov 2020 00:02:34
User entered 'No (N)'	System	28 Nov 2020 00:02:34

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-11-27T19:02:15', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '361a5286-544d-496d-8f31-ca2fe7d9c11f'	System	28 Nov 2020 00:02:34
User entered 'No (N)'	System	28 Nov 2020 00:02:34

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-11-27T19:02:28', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '361a5286-544d-496d-8f31-ca2fe7d9c11f' User entered '27 Nov 2020 19:02:28'	System	28 Nov 2020 00:02:34

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-12-04T14:40:34', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '92ce28fa-708e-4ddd-992c-6dea07598be1'	System	04 Dec 2020 19:41:09
User entered 'No (N)'	System	04 Dec 2020 19:41:09

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-12-04T14:40:42', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '92ce28fa-708e-4ddd-992c-6dea07598be1'	System	04 Dec 2020 19:41:09
User entered 'No (N)'	System	04 Dec 2020 19:41:09

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-12-04T14:41:06', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '92ce28fa-708e-4ddd-992c-6dea07598be1' User entered '04 Dec 2020 14:41:06'	System	04 Dec 2020 19:41:09
	System	04 Dec 2020 19:41:09

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-12-11T10:32:25', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a7fb4819-7aa8-475d-a928-8c0b37aa6c40'	System	11 Dec 2020 15:32:55
User entered 'No (N)'	System	11 Dec 2020 15:32:55

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-12-11T10:32:33', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a7fb4819-7aa8-475d-a928-8c0b37aa6c40'	System	11 Dec 2020 15:32:55
User entered 'No (N)'	System	11 Dec 2020 15:32:55

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-12-11T10:32:49', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'a7fb4819-7aa8-475d-a928-8c0b37aa6c40'	System	11 Dec 2020 15:32:55
User entered '11 Dec 2020 10:32:49'	System	11 Dec 2020 15:32:55

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-12-18T18:43:39', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'e1d520af-9cf9-4cca-96f7-f40dec8ee770'	System	18 Dec 2020 23:44:26
User entered 'No (N)'	System	18 Dec 2020 23:44:26

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-12-18T18:43:47', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'e1d520af-9cf9-4cca-96f7-f40dec8ee770'	System	18 Dec 2020 23:44:26
User entered 'No (N)'	System	18 Dec 2020 23:44:26

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-12-18T18:44:23', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'e1d520af-9cf9-4cca-96f7-f40dec8ee770'	System	18 Dec 2020 23:44:26
User entered '18 Dec 2020 18:44:23'	System	18 Dec 2020 23:44:26

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2020-12-23T11:58:34', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ab9602e3-19c1-4cc1-a35a-3363ce9c84b2'	System	23 Dec 2020 16:58:59
User entered 'No (N)'	System	23 Dec 2020 16:58:59

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2020-12-23T11:58:40', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ab9602e3-19c1-4cc1-a35a-3363ce9c84b2'	System	23 Dec 2020 16:58:59
User entered 'No (N)'	System	23 Dec 2020 16:58:59

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2020-12-23T11:58:52', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ab9602e3-19c1-4cc1-a35a-3363ce9c84b2'	System	23 Dec 2020 16:58:59
User entered '23 Dec 2020 11:58:52'	System	23 Dec 2020 16:58:59

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-01-01T13:01:20', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ffbd05de-fb3a-4977-8220-c9bd502d34f9'	System	01 Jan 2021 18:01:47
User entered 'No (N)'	System	01 Jan 2021 18:01:47

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-01-01T13:01:28', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ffbd05de-fb3a-4977-8220-c9bd502d34f9'	System	01 Jan 2021 18:01:47
User entered 'No (N)'	System	01 Jan 2021 18:01:47

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-01-01T13:01:43', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ffbd05de-fb3a-4977-8220-c9bd502d34f9' User entered '01 Jan 2021 13:01:43'	System	01 Jan 2021 18:01:47
	System	01 Jan 2021 18:01:47

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-01-09T12:05:39', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '03be600d-2797-4d31-bac9-0289fd275da7'	System	09 Jan 2021 17:06:17
User entered 'No (N)'	System	09 Jan 2021 17:06:17

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-01-09T12:05:45', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '03be600d-2797-4d31-bac9-0289fd275da7'	System	09 Jan 2021 17:06:17
User entered 'Yes (Y)'	System	09 Jan 2021 17:06:17

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Please 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 (b3c728fb16ca332c)', Time: '2021-01-09T12:05:52', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '03be600d-2797-4d31-bac9-0289fd275da7'	System	09 Jan 2021 17:06:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 17:06:17

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-01-09T12:06:06', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '03be600d-2797-4d31-bac9-0289fd275da7'	System	09 Jan 2021 17:06:17
User entered '09 Jan 2021 12:06:06'	System	09 Jan 2021 17:06:17

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-01-15T20:29:19', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7cb33f31-8a9f-4f1e-bd34-6d466f5df0a2'	System	16 Jan 2021 01:29:54
User entered 'No (N)'	System	16 Jan 2021 01:29:54

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-01-15T20:29:45', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7cb33f31-8a9f-4f1e-bd34-6d466f5df0a2'	System	16 Jan 2021 01:29:54
User entered 'No (N)'	System	16 Jan 2021 01:29:54

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-01-15T20:29:51', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7cb33f31-8a9f-4f1e-bd34-6d466f5df0a2'	System	16 Jan 2021 01:29:54
User entered '15 Jan 2021 20:29:51'	System	16 Jan 2021 01:29:54

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-01-22T12:42:21', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b5770774-4ee2-41bc-bba5-db24ecabad11'	System	22 Jan 2021 17:42:35
User entered 'No (N)'	System	22 Jan 2021 17:42:35

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-01-22T12:42:26', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b5770774-4ee2-41bc-bba5-db24ecabad11'	System	22 Jan 2021 17:42:35
User entered 'No (N)'	System	22 Jan 2021 17:42:35

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-01-22T12:42:32', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b5770774-4ee2-41bc-bba5-db24ecabad11'	System	22 Jan 2021 17:42:35
User entered '22 Jan 2021 12:42:32'	System	22 Jan 2021 17:42:35

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-01-29T18:35:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '39b3c2c2-4320-4be2-b811-38678ef3dac8'	System	29 Jan 2021 23:35:21
User entered 'No (N)'	System	29 Jan 2021 23:35:21

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-01-29T18:35:11', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '39b3c2c2-4320-4be2-b811-38678ef3dac8'	System	29 Jan 2021 23:35:21
User entered 'No (N)'	System	29 Jan 2021 23:35:21

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-01-29T18:35:18', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '39b3c2c2-4320-4be2-b811-38678ef3dac8' User entered '29 Jan 2021 18:35:18'	System	29 Jan 2021 23:35:21
	System	29 Jan 2021 23:35:21

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-02-07T07:58:48', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2221f6f6-7c1e-49af-a24e-102e9d21d359'	System	07 Feb 2021 12:59:19
User entered 'No (N)'	System	07 Feb 2021 12:59:19

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-02-07T07:58:58', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2221f6f6-7c1e-49af-a24e-102e9d21d359'	System	07 Feb 2021 12:59:19
User entered 'No (N)'	System	07 Feb 2021 12:59:19

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-07T07:59:14', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '2221f6f6-7c1e-49af-a24e-102e9d21d359'	System	07 Feb 2021 12:59:19
User entered '07 Feb 2021 07:59:14'	System	07 Feb 2021 12:59:19

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-02-13T15:48:23', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5ba95cdf-23e9-43c6-a90b-665a606acd13'	System	13 Feb 2021 20:48:43
User entered 'No (N)'	System	13 Feb 2021 20:48:43

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-02-13T15:48:31', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5ba95cdf-23e9-43c6-a90b-665a606acd13'	System	13 Feb 2021 20:48:43
User entered 'No (N)'	System	13 Feb 2021 20:48:43

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-13T15:48:37', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5ba95cdf-23e9-43c6-a90b-665a606acd13'	System	13 Feb 2021 20:48:43
User entered '13 Feb 2021 15:48:37'	System	13 Feb 2021 20:48:43

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-02-19T20:17:41', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ed7ec1e9-ca3f-4bb8-8e58-d109dd0d92d9'	System	20 Feb 2021 01:18:08
User entered 'No (N)'	System	20 Feb 2021 01:18:08

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-02-19T20:17:49', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ed7ec1e9-ca3f-4bb8-8e58-d109dd0d92d9'	System	20 Feb 2021 01:18:08
User entered 'No (N)'	System	20 Feb 2021 01:18:08

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-19T20:17:58', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ed7ec1e9-ca3f-4bb8-8e58-d109dd0d92d9'	System	20 Feb 2021 01:18:08
User entered '19 Feb 2021 20:17:58'	System	20 Feb 2021 01:18:08

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-02-27T18:31:00-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '80ef6a41-df39-40cd-b078-d13112f91e03'	System	27 Feb 2021 23:31:38
User entered 'No (N)'	System	27 Feb 2021 23:31:38

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-02-27T18:31:17-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '80ef6a41-df39-40cd-b078-d13112f91e03'	System	27 Feb 2021 23:31:38
User entered 'No (N)'	System	27 Feb 2021 23:31:38

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-27T18:31:33-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '80ef6a41-df39-40cd-b078-d13112f91e03'	System	27 Feb 2021 23:31:38
User entered '27 Feb 2021 18:31:33'	System	27 Feb 2021 23:31:38

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-03-06T12:08:02-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '38d3c178-cb3f-4a83-aad9-05d4466cd4f8'	System	06 Mar 2021 17:15:46
User entered 'No (N)'	System	06 Mar 2021 17:15:46

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-03-06T12:08:08-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '38d3c178-cb3f-4a83-aad9-05d4466cd4f8'	System	06 Mar 2021 17:15:46
User entered 'No (N)'	System	06 Mar 2021 17:15:46

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-03-06T12:08:18-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '38d3c178-cb3f-4a83-aad9-05d4466cd4f8'	System	06 Mar 2021 17:15:46
User entered '06 Mar 2021 12:08:18'	System	06 Mar 2021 17:15:46

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-03-12T17:53:47-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f8ef816-6bc8-4a29-b506-dfb6c4f8d864'	System	12 Mar 2021 22:54:06
User entered 'No (N)'	System	12 Mar 2021 22:54:06

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-03-12T17:53:52-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f8ef816-6bc8-4a29-b506-dfb6c4f8d864'	System	12 Mar 2021 22:54:06
User entered 'No (N)'	System	12 Mar 2021 22:54:06

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-03-12T17:54:00-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '7f8ef816-6bc8-4a29-b506-dfb6c4f8d864'	System	12 Mar 2021 22:54:06
User entered '12 Mar 2021 17:54:00'	System	12 Mar 2021 22:54:06

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-03-20T13:59:09-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '11257fed-fbad-4984-8e42-0a5ea591c779'	System	20 Mar 2021 17:59:33
User entered 'No (N)'	System	20 Mar 2021 17:59:33

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-03-20T13:59:20-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '11257fed-fbad-4984-8e42-0a5ea591c779'	System	20 Mar 2021 17:59:33
User entered 'No (N)'	System	20 Mar 2021 17:59:33

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-03-20T13:59:28-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '11257fed-fbad-4984-8e42-0a5ea591c779' User entered '20 Mar 2021 13:59:28'	System	20 Mar 2021 17:59:33

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-03-26T14:38:04-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5e961a34-8e87-4cd7-a095-93325ef58b7d' User entered 'No (N)'	System	26 Mar 2021 18:38:22
	System	26 Mar 2021 18:38:22

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-03-26T14:38:12-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5e961a34-8e87-4cd7-a095-93325ef58b7d'	System	26 Mar 2021 18:38:22
User entered 'No (N)'	System	26 Mar 2021 18:38:22

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-03-26T14:38:18-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '5e961a34-8e87-4cd7-a095-93325ef58b7d' User entered '26 Mar 2021 14:38:18'	System	26 Mar 2021 18:38:22
	System	26 Mar 2021 18:38:22

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-04-02T20:22:59-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ac0eacb0-e693-4d95-9165-a0fa43313d38'	System	03 Apr 2021 00:23:13
User entered 'No (N)'	System	03 Apr 2021 00:23:13

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-04-02T20:23:04-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ac0eacb0-e693-4d95-9165-a0fa43313d38'	System	03 Apr 2021 00:23:13
User entered 'No (N)'	System	03 Apr 2021 00:23:13

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-04-02T20:23:10-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'ac0eacb0-e693-4d95-9165-a0fa43313d38'	System	03 Apr 2021 00:23:13
User entered '02 Apr 2021 20:23:10'	System	03 Apr 2021 00:23:13

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-04-08T13:19:31-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'c107847d-9e9f-459a-9580-567ff8e653ed'	System	08 Apr 2021 17:19:51
User entered 'No (N)'	System	08 Apr 2021 17:19:51

US3242258

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:30

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-04-08T13:19:38-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'c107847d-9e9f-459a-9580-567ff8e653ed'	System	08 Apr 2021 17:19:51
User entered 'No (N)'	System	08 Apr 2021 17:19:51

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-04-08T13:19:47-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'c107847d-9e9f-459a-9580-567ff8e653ed' User entered '08 Apr 2021 13:19:47'	System	08 Apr 2021 17:19:51
	System	08 Apr 2021 17:19:51

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-04-16T21:09:54-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b89bccb1-b755-4502-85a4-4f0b6b3fde8c' User entered 'No (N)'	System	17 Apr 2021 01:12:03
	System	17 Apr 2021 01:12:03

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-04-16T21:10:01-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b89bccb1-b755-4502-85a4-4f0b6b3fde8c'	System	17 Apr 2021 01:12:03
User entered 'No (N)'	System	17 Apr 2021 01:12:03

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-04-16T21:10:06-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'b89bccb1-b755-4502-85a4-4f0b6b3fde8c'	System	17 Apr 2021 01:12:03
User entered '16 Apr 2021 21:10:06'	System	17 Apr 2021 01:12:03

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-04-24T19:56:54-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0b1e14bb-694e-4781-b27c-f7c39a65c669' User entered 'No (N)'	System	24 Apr 2021 23:57:10
	System	24 Apr 2021 23:57:10

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-04-24T19:57:00-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0b1e14bb-694e-4781-b27c-f7c39a65c669'	System	24 Apr 2021 23:57:10
User entered 'No (N)'	System	24 Apr 2021 23:57:10

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-04-24T19:57:06-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '0b1e14bb-694e-4781-b27c-f7c39a65c669' User entered '24 Apr 2021 19:57:06'	System	24 Apr 2021 23:57:10
	System	24 Apr 2021 23:57:10

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[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 (b3c728fb16ca332c)', Time: '2021-04-30T20:06:28-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '560969dd-e17e-4e10-ad3a-911c4d33a658'	System	01 May 2021 00:06:50
User entered 'No (N)'	System	01 May 2021 00:06:50

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Have you been exposed to someone with 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 (b3c728fb16ca332c)', Time: '2021-04-30T20:06:35-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '560969dd-e17e-4e10-ad3a-911c4d33a658'	System	01 May 2021 00:06:50
User entered 'No (N)'	System	01 May 2021 00:06:50

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-04-30T20:06:42-04:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: '560969dd-e17e-4e10-ad3a-911c4d33a658' User entered '30 Apr 2021 20:06:42'	System	01 May 2021 00:06:50
	System	01 May 2021 00:06:50

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:05:53

**US3242258**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:05:53

**US3242258**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:05:53

**US3242258**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:53
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:05:53

US3242258

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:09:30**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-27T18:31:50-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd09973e8-528e-41ee-b76c-a3aa512209e1'	(b) (4), (b) (6)	27 Feb 2021 23:32:06
User entered 'No (N)'	System	27 Feb 2021 23:32:06

**US3242258**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:42:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3c728fb16ca332c)', Time: '2021-02-27T18:32:01-05:00', User OID: 'PatientReportedOutcome (US3242258)', ODM File OID: 'd09973e8-528e-41ee-b76c-a3aa512209e1' User entered '27 Feb 2021 18:32:01'	(b) (4), (b) (6) System	27 Feb 2021 23:32:06
	System	27 Feb 2021 23:32:06

**US3242258**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Dec 2020 14:40:39
	(b) (4)	

US3242258

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '30 Nov 2020'	Erynn McKinley (b) (4)	01 Dec 2020 14:40:39
	(b) (4)	

US3242258

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	01 Dec 2020 14:40:39
	(b) (4)	

US3242258

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	01 Dec 2020 14:40:39
	(b) (4)	

US3242258

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Dec 2020 14:40:42
	(b) (4)	

US3242258

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:49:52
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 14:40:42
	System	

US3242258

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Dec 2020 22:18:36
	(b) (4)	

US3242258

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '28 Dec 2020'	Erynn McKinley (b) (4)	28 Dec 2020 22:18:36
	(b) (4)	

US3242258

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	28 Dec 2020 22:18:36
	(b) (4)	

US3242258

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	28 Dec 2020 22:18:36
	(b) (4)	

US3242258

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Dec 2020 22:18:40
	(b) (4)	

US3242258

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered '1'	(b) (4), (b) (6) System	28 Dec 2020 22:18:40

US3242258

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Jan 2021 15:09:50
	(b) (4)	

US3242258

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '25 Jan 2021'	Erynn McKinley (b) (4)	25 Jan 2021 15:09:50
	(b) (4)	

US3242258

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	25 Jan 2021 15:09:50
	(b) (4)	

US3242258

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	25 Jan 2021 15:09:50
	(b) (4)	

US3242258

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Jan 2021 15:09:54
	(b) (4)	

**US3242258**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered '1'	(b) (4), (b) (6) System	25 Jan 2021 15:09:54

US3242258

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	24 Feb 2021 21:18:34
	(b) (4)	

US3242258

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '24 Feb 2021'	Erynn McKinley (b) (4)	24 Feb 2021 21:18:34
	(b) (4)	

US3242258

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	24 Feb 2021 21:18:34
	(b) (4)	

US3242258

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4)	24 Feb 2021 21:18:34
	(b) (4)	

US3242258

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	24 Feb 2021 21:18:37
	(b) (4)	

US3242258

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered '1'	(b) (4), (b) (6) System	24 Feb 2021 21:18:37

US3242258

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:35
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '25 Mar 2021'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:35
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

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 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:35
	(b) (4)	

**US3242258**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered 'VISIT4'	(b) (4), (b) (6) System	25 Mar 2021 18:45:35

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:54:23

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:54:23

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:54:23

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:54:23

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:58:14
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:54:23
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:54:23

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:53:20

US3242258

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:53:20

US3242258

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:45
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:45:45
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:54
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '25 Mar 2021'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:54
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '14:09'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:54
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered '25 Mar 2021 14:09'	(b) (4), (b) (6) System	25 Mar 2021 18:45:54

US3242258

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Mar 2021 18:45:57
	(b) (4)	

US3242258

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:53:20
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 18:45:57

US3242258

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:18:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:55:47

US3242258

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:18:40
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:55:47

US3242258

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:18:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:55:47

**US3242258**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:09:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:18:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:55:47

US3242258

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:18:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:55:53

**US3242258**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 18:55:53

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:36
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:36
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:36
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	14 Jan 2021 18:06:36

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 16:06:56
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:38:33

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 09:11:21
	(b) (4), (b) (6)	
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject did not receive dose 2 due to having pneumonia' (Site from System).	Donna Toepfer (b) (4)	14 Jan 2021 18:11:39
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 18:11:21
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 18:11:07
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	14 Jan 2021 18:11:07
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 18:06:56
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 16:06:56
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 07:38:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Placebo (Placebo)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 03:48:19
User entered 'Placebo (Placebo)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:07:01
Signature has been broken.	Erynn McKinley (b) (4)	22 Feb 2021 22:01:23
	(b) (4)	
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Feb 2021 22:01:23
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	14 Jan 2021 18:14:39
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Jan 2021 18:11:46
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	14 Jan 2021 18:11:21
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	14 Jan 2021 18:11:07
User entered empty.	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 18:06:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User entered '1'	System	22 Feb 2021 22:01:23
User entered empty.	System	14 Jan 2021 18:14:39
User entered '1'	System	14 Jan 2021 18:11:46
User entered empty.	System	14 Jan 2021 18:11:21
User entered '1'	System	14 Jan 2021 18:11:07
User entered empty.	System	14 Jan 2021 18:06:56

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User entered 'I'	System	22 Feb 2021 22:01:23
User entered empty.	System	14 Jan 2021 18:14:39
User entered 'I'	System	14 Jan 2021 18:11:46
User entered empty.	System	14 Jan 2021 18:11:21
User entered 'I'	System	14 Jan 2021 18:11:07
User entered empty.	System	14 Jan 2021 18:06:56

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
DataPoint set to visible.	System	22 Feb 2021 22:01:23
DataPoint set to invisible.	System	14 Jan 2021 18:14:39
User entered empty.	System	14 Jan 2021 18:13:42
DataPoint set to visible.	System	14 Jan 2021 18:11:46

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
DataPoint set to visible.	System	22 Feb 2021 22:01:23
DataPoint set to invisible.	System	14 Jan 2021 18:14:39
User entered empty.	System	14 Jan 2021 18:13:42
DataPoint set to visible.	System	14 Jan 2021 18:11:46

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '11:19'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '14 Jan 2021 11:19'	(b) (4), (b) (6) System	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '98.4' F	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '68'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'bpm'	(b) (4), (b) (6) System	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '16'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '124'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '64'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:42

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
DataPoint set to visible.	System	22 Feb 2021 22:01:23
DataPoint set to invisible.	System	14 Jan 2021 18:14:39
User entered empty.	System	14 Jan 2021 18:13:42
DataPoint set to visible.	System	14 Jan 2021 18:11:46

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '12:39'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '14 Jan 2021 12:39'	(b) (4), (b) (6) System	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '97.6' F	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '64'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'bpm'	(b) (4), (b) (6) System	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '16'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '128'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '76'	Donna Toepfer (b) (4)	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 18:14:13

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Donna Toepfer (b) (4)	14 Jan 2021 18:13:02

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	14 Jan 2021 18:13:02

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

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)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
DataPoint set to visible.	System	22 Feb 2021 22:01:23
DataPoint set to invisible.	System	14 Jan 2021 18:14:39
User entered 'mRNA-1273'	System	14 Jan 2021 18:12:38
DataPoint set to visible.	System	14 Jan 2021 18:11:46

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '12:08'	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '14 Jan 2021 12:08'	(b) (4), (b) (6) System	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'ONCE'	(b) (4), (b) (6) System	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Jan 2021 18:12:38

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 18:09:40
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Erynn McKinley (b) (4)	14 Jan 2021 18:09:40
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '11:09'	Erynn McKinley (b) (4)	14 Jan 2021 18:09:40
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '14 Jan 2021 11:09'	(b) (4), (b) (6) System	14 Jan 2021 18:09:40

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 18:09:54
	(b) (4)	

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '14 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	14 Jan 2021 18:09:54

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '11:06'	Erynn McKinley (b) (4)	14 Jan 2021 18:09:54
	(b) (4)	

**US3242258**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:09:30**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '14 Jan 2021 11:06'	(b) (4), (b) (6) System	14 Jan 2021 18:09:54

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Jan 2021 18:12:44

US3242258

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '1'	(b) (4), (b) (6) System	14 Jan 2021 18:12:44

**US3242258**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	21 Jan 2021 16:20:49

US3242258

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '21 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	21 Jan 2021 16:20:49

US3242258

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	21 Jan 2021 16:20:49

US3242258

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4) (b) (4)	21 Jan 2021 16:20:49

US3242258

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	21 Jan 2021 16:20:54

**US3242258**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'I'	(b) (4), (b) (6) System	21 Jan 2021 16:20:54

**US3242258**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 16:20:54
DataPoint set to visible.	System	21 Jan 2021 16:20:54

US3242258

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:43:40

US3242258

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '11 Feb 2021'	Erynn McKinley (b) (4)	11 Feb 2021 20:43:40
	(b) (4)	

US3242258

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:43:40

**US3242258**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'OLD29'	(b) (4), (b) (6) System	11 Feb 2021 20:43:40

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '11 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '13:29'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '11 Feb 2021 13:29'	(b) (4), (b) (6) System	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '98.2' F	Erynn McKinley (b) (4)	11 Feb 2021 20:44:09
	(b) (4)	

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	11 Feb 2021 20:44:09
	(b) (4)	

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '64'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'bpm'	(b) (4), (b) (6) System	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '18'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '132'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered '76'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 20:44:09

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 10:30:18

US3242258

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 10:30:18

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	22 Feb 2021 22:02:48
	(b) (4)	

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:03:07
User entered '11 Feb 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:07
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:02:48
User entered '22 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '13:29'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '11 Feb 2021 13:29'	(b) (4), (b) (6)	
	System	22 Feb 2021 22:03:07
User entered '22 Feb 2021 13:29'	System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '98.2' F	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '64'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '18'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '132'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '76'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered missing code ND - Not Done.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:03:07
User entered '11 Feb 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:07
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:02:48
User entered '22 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '14:32'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '11 Feb 2021 14:32'	(b) (4), (b) (6)	
	System	22 Feb 2021 22:03:07
User entered '22 Feb 2021 14:32'	System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '98.0' F	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '60'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

**US3242258**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '16'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '134'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '78'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 22:02:48

US3242258

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	11 Feb 2021 20:44:14

US3242258

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	11 Feb 2021 20:44:14
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

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)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	22 Feb 2021 22:03:25

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:03:34
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	22 Feb 2021 22:03:34
User entered '11 Feb 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:34
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Feb 2021 22:03:25
User entered '22 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '13:57'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '11 Feb 2021 13:57'	(b) (4), (b) (6)	
	System	22 Feb 2021 22:03:34
User entered '22 Feb 2021 13:57'	System	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'ONCE'	(b) (4), (b) (6) System	22 Feb 2021 22:03:25

US3242258

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	22 Feb 2021 22:03:25

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Erynn McKinley (b) (4)	11 Feb 2021 20:44:20
	(b) (4)	

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	11 Feb 2021 20:44:20
	(b) (4)	

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User entered empty.	Erynn McKinley (b) (4)	11 Feb 2021 20:44:20
	(b) (4)	

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	11 Feb 2021 20:44:20

US3242258

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:03:38

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 22:03:38

**US3242258**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:09:24

US3242258

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered '19 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:09:24

US3242258

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:09:24

US3242258

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:09:24

US3242258

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:07:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	22 Feb 2021 22:09:28

**US3242258**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 22:09:28

**US3242258**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:25
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '25 Mar 2021'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:25
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	25 Mar 2021 18:46:25

**US3242258**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered 'OLD57'	(b) (4), (b) (6) System	25 Mar 2021 18:46:25

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	25 Mar 2021 18:46:35

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 18:46:35

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 18:46:35

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 18:46:35

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Mar 2021 18:46:35

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 18:46:35

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:35
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 18:46:35

**US3242258**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:09:30**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 10:30:18

US3242258

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 10:30:18

US3242258

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:44
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered empty.	Erynn McKinley (b) (4)	25 Mar 2021 18:46:44
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:54
	(b) (4)	

US3242258

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '25 Mar 2021'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:54
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:09:30**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	29 Mar 2021 14:04:03
User entered '14:09'	Erynn McKinley (b) (4)	25 Mar 2021 18:46:54
	(b) (4)	

**US3242258**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:09:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:30:18
User entered '25 Mar 2021 14:09'	(b) (4), (b) (6) System	25 Mar 2021 18:46:54

US3242258

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:09:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:41:25
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:31:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	25 Sep 2020 17:41:51
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:18:58

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:09:30**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:44:50
Data point term sent to Coder	System	25 Sep 2020 17:44:10
User entered 'Fatigue'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '2 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User entered empty.	System	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '7 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:09:30**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User entered empty.	System	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Related (RELATED)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Related (RELATED)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'None (NONE)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'I'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

US3242258

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:43:59

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User entered '0'	System	25 Sep 2020 17:43:59

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17
User entered '0'	System	25 Sep 2020 17:43:59

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:49:17

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Per MM, please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 14:35:01
	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Community acquired pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:47:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Nov 2020 14:47:25
Data point term sent to Coder	System	05 Nov 2020 14:46:14
Coding entries removed.	Donna Toepfer (b) (4)	05 Nov 2020 14:45:44
User entered 'Community Acquired PNEUMONIA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Nov 2020 14:45:44
Query 'Per MM, please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' answered with 'not evaluated for covid' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 15:39:32
User opened query 'Per MM, please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 17:50:56
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:48:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Sep 2020 17:48:58
Data point term sent to Coder	System	25 Sep 2020 17:48:19
User entered 'Pneumonia'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21
	(b) (4)	

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '15 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User entered empty.	System	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Nov 2020 14:45:44
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:09:30**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '22 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Nov 2020 14:45:44
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4) (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User entered empty.	System	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query ' Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:07:40
Query ' Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 15:42:17
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 15:42:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 15:42:10
User opened query ' Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:20:30
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'None (NONE)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'I'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Nov 2020 14:45:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

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 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 17:47:21

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User entered '0'	System	25 Sep 2020 17:47:21

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51
User entered 'I'	System	25 Sep 2020 17:47:21

US3242258

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:01:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:01:52
Data point term sent to Coder	System	01 Dec 2020 21:00:57
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Dec 2020 21:00:11
Coding entries removed.	Donna Toepfer (b) (4)	01 Dec 2020 21:00:11
User entered 'Asthma Exacerbation' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Dec 2020 21:00:11
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 05:12:13
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 05:12:13
Data point term sent to Coder	System	02 Nov 2020 21:47:17
User entered 'Asthma, Severe Persistent'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '5 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User entered empty.	System	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Un-verified.	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Un-verified.	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
User entered '22 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:09:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User entered empty.	System	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Dose Delayed (DOSE DELAYED)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'I'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Un-verified.	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Erynn McKinley (b) (4)	15 Dec 2020 21:38:21
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

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 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:36:22
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:46:39

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User entered '0'	System	02 Nov 2020 21:46:39

**US3242258**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30
User entered 'I'	System	02 Nov 2020 21:46:39

US3242258

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:34:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:09:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:41:25
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:37:17
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:39:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
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)	31 Aug 2020 18:41:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:41:38
Data point term sent to Coder	System	31 Aug 2020 18:41:16
User entered 'Lipitor'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Coronary Artery Disease'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '80'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '1 Jan 2015'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Donna Toepfer (b) (4)	31 Aug 2020 18:41:12

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:41:12

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 18:41:12

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 18:41:12

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 04:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 04:54:54
Data point term sent to Coder	System	28 Sep 2020 19:18:33
User entered 'Zithromax'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Pneumonia'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '500'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '16 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '16 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:17:41

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User entered empty.	System	28 Sep 2020 19:17:41

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User entered empty.	System	28 Sep 2020 19:17:41

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:13:57
User entered empty.	System	28 Sep 2020 19:17:41

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 19:25:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 19:25:39
Data point term sent to Coder	System	28 Sep 2020 19:24:53
User entered 'Mucinex'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Pneumonia'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '600'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:09:30**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '16 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:29:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 17:17:11
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 17:17:05
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 17:17:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:30:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 17:17:05
User entered '22 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 17:17:05
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:24:28

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User entered '2'	System	28 Sep 2020 19:24:28

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User entered '1'	System	28 Sep 2020 19:24:28

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:20
User entered '804 (804)'	System	28 Sep 2020 19:24:28

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROM/PSE/DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 19:26:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 19:26:46
Data point term sent to Coder	System	28 Sep 2020 19:25:54
User entered 'Brom/PSE/DM'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Pneumonia'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '10'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '16 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:30:07
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 17:17:35
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 17:17:30
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 17:17:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:31:12
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 17:17:30
User entered '22 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 17:17:30
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:25:24

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User entered empty.	System	28 Sep 2020 19:25:24

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User entered empty.	System	28 Sep 2020 19:25:24

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:31
User entered empty.	System	28 Sep 2020 19:25:24

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 04:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 04:54:54
Data point term sent to Coder	System	28 Sep 2020 19:28:03
User entered 'Zithromax'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Pneumonia'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '250'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '17 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '20 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 19:28:03

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User entered '1'	System	28 Sep 2020 19:28:03

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User entered '1'	System	28 Sep 2020 19:28:03

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:14:47
User entered '804 (804)'	System	28 Sep 2020 19:28:03

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE MONOHYDRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 05:23:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 05:23:14
Data point term sent to Coder	System	02 Nov 2020 21:49:19
User entered 'Doxycycline Monohydrate'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Asthma'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '100'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '5 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '15 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:48:45

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User entered '2'	System	02 Nov 2020 21:48:45

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User entered '1'	System	02 Nov 2020 21:48:45

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:03
User entered '804 (804)'	System	02 Nov 2020 21:48:45

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:22:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:22:28
Data point term sent to Coder	System	02 Nov 2020 21:50:21
User entered 'Prednisone'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Asthma'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '40'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Nov 2020 21:50:36
User entered '05 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	02 Nov 2020 21:50:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Nov 2020 21:49:54
User entered '05 2020' (non-conformant).	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '09 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:49:54

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User entered '1'	System	02 Nov 2020 21:49:54

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User entered '1'	System	02 Nov 2020 21:49:54

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:18
User entered '804 (804)'	System	02 Nov 2020 21:49:54

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:28:41
Data point term sent to Coder	System	02 Nov 2020 21:52:24
User entered 'Prednisone'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Asthma'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '20'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '10 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:51:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User entered 'I'	System	02 Nov 2020 21:51:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User entered '1'	System	02 Nov 2020 21:51:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:15:29
User entered '804 (804)'	System	02 Nov 2020 21:51:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
	Coder Import (b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL - version WHODrug-Global-B3\\202003.	(b) (4)	03 Nov 2020 05:15:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 05:15:15
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 21:54:27
User entered 'Budesonide / Formoterol Aerosol'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Asthma'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '160 / 4.5'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'ug (ug)'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Erynn McKinley (b) (4)	02 Nov 2020 21:53:30
	(b) (4)	

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '08 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:53:30

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Nov 2020 21:53:30

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:53:30

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 21:53:30

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
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)	05 Nov 2020 15:35:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:35:41
Data point term sent to Coder	System	02 Nov 2020 21:54:27
User entered 'Aspirin'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Prophylaxis for heart health'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '81'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'UN UNK 2015'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:54:21

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 21:54:21

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:39:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:39:13
Data point term sent to Coder	System	02 Nov 2020 21:55:28
User entered 'Calcium'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Prophylaxis for Bone Health'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '80'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'once daily (QD)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'UN UNK 2015'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 21:55:23

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 21:55:23

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:46:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:46:18
Data point term sent to Coder	System	02 Nov 2020 21:57:31
User entered 'Albuterol'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'COPD'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '90'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'mcg / 2 puffs'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:09:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'UN UNK 2010'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 21:56:37

US3242258

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:09:30**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:19:45
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	09 Feb 2021 20:29:27

US3242258

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:30

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:43:40
User entered '5 Nov 2020'	Donna Toepfer (b) (4)	05 Nov 2020 14:57:35

US3242258

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:43:40
User entered 'AE (specify) (ADVERSE EVENT)'	Donna Toepfer (b) (4)	05 Nov 2020 14:57:35

US3242258

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:30

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:42
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:19:45
User closed query 'Per CDM: please record AE record number instead of details.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:18:43
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	19 Nov 2020 13:43:40
Query 'Per CDM: please record AE record number instead of details.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Nov 2020 14:44:01
User entered 'AE #2' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Nov 2020 14:43:54
User opened query 'Per CDM: please record AE record number instead of details.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:43:06
User entered 'Community Acquired Pneumonia'	Donna Toepfer (b) (4)	05 Nov 2020 14:57:35